

# EXHIBIT B

Marc R. Toggia, M.D.

Page 1

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

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IN RE: ETHICON, INC., :MASTER FILE NO.  
PELVIC REPAIR SYSTEM PRODUCTS :2:12-MD-02327  
LIABILITY LITIGATION :MDL 2327  
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THIS DOCUMENT RELATES TO THE :  
FOLLOWING CASES IN WAVE 1 OF :  
THE MDL 200: :  
Betty Funderburke :JOSEPH R. GOODWIN  
Case No. 2:12-cv-00957 :U.S. DISTRICT JUDGE  
:  
Patricia Conti :  
Case No. 2:12-cv-00516 :  
:  
Donna Massey :  
Case No. 2:12-cv-00880 :  
:  
Amanda Deleon :  
Case No. 2:12-cv-00358 :  
:  
Wilma Johnson :  
Case No. 2:12-cv-00809 :  
:  
Harriet Beach :  
Case No. 2:12-cv-00476 :  
:  
Virginia Dixon :  
Case No. 2:12-cv-01081 :  
:  
-----

March 24, 2016

DEPOSITION OF MARC R. TOGLIA, M.D.

GOLKOW TECHNOLOGIES, INC.  
877.370.3377 ph | 917.591.5672 fax  
deps@golkow.com

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March 24, 2016

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Oral sworn deposition of MARC R. TOGLIA,  
M.D., held at RADNOR HOTEL, 591 East Lancaster  
Avenue, Wayne, Pennsylvania, commencing at 1:20  
p.m., before Margaret M. Reihl, a Registered  
Professional Reporter, Certified Realtime  
Reporter, and Notary Public.

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1 A P P E A R A N C E S:

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1 I N D E X

2 WITNESS: Page  
 3 MARC R. TOGLIA, M.D.

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 5 By Mr. Snell 254

6 E X H I B I T S

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 10 No. 2 Curriculum Vitae of  
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 11 No. 3 Website printout of  
 12 Urogynecology Associates of  
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 14 No. 5 Invoices of Marc R. Toggia,  
 15 (two pages) 77  
 16 No. 6 Expert Report of Marc R. Toggia,  
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 17 No. 7 Marc Toggia Reliance List in  
 18 Addition to Materials Referenced  
 in Report 79  
 19 No. 8 E-mail string, top one dated  
 20 7/21/09  
 [ETH.MESH.00585587 through 585589] 90  
 21 No. 9 E-mail string, top one dated  
 22 1/26/10  
 [ETH.MESH.01221280 through 01221283] 101  
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| 3  |        | [ETH.MESH.02342218 through 02342249]   | 141 |
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| 5  |        | [ETH.MESH.01177099]  | 163 |
| 6  | No. 13 | E-mail string, top one dated 11/30/10<br>[ETH.MESH.05131435 through 05131436]                            | 177 |
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1                   ... MARC R. TOGLIA, M.D., having been duly  
2                   sworn as a witness, was examined and testified  
3                   as follows ...

4   BY MR. SCHNIEDERS:

5           Q.       Good afternoon, Doctor.

6           A.       Good afternoon.

7           Q.       My name is Chris Schnieders, and I'm  
8           here on behalf of the plaintiff steering committee to  
9           take your deposition based upon an expert report that  
10          you wrote for a couple of products.

11          Do you understand that today?

12          A.       Yes.

13          Q.       Would you please state your name for the  
14          record.

15          A.       Mark Richard Toggia.

16          Q.       And I believe, Dr. Toggia, that you have  
17          given a deposition related to your TVT report already;  
18          is that correct?

19          A.       That is correct.

20          Q.       And you understand that we are here  
21          today on the Gynemesh PS and Prolift report that you  
22          had written?

23          A.       Yes, I do.

24          Q.       Doctor, I'm going to mark as Exhibit 1



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1 the notice that has asked you to come here today and  
2 hand it to you.

3 A. Sure.

4 (Document marked for identification as  
5 Toggia Deposition Exhibit No. 1.)

6 BY MR. SCHNIEDERS:

7 Q. Have you seen this document before,  
8 Doctor?

9 A. I have.

10 Q. And we were talking about this briefly  
11 beforehand, but you've brought some documents with you  
12 here today; is that correct?

13 A. Yes, I have.

14 Q. Okay. I'm going to go through Schedule  
15 A, and you just tell me what you brought today that is  
16 responsive to those things, and I'm going to ask you  
17 some questions on if there are other things that you  
18 haven't brought today that are responsive as well,  
19 okay?

20 A. Yes.

21 Q. Number 1, this is on Page 7, a complete  
22 copy of your Curriculum Vitae?

23 A. I believe that's part of my expert  
24 report.

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1           Q.       Number 2, "Any and all documents in your  
2   possession, including but not limited to,  
3   correspondence, notes, videos, CDs, DVDs, flash or USB  
4   drives, photographs, databases or materials in other  
5   form provided to you or created by you which relate to  
6   your opinions, expected testimony or development of  
7   your opinions in this litigation."

8           A.       Yes.

9           Q.       Have you brought everything that you  
10   believe that you have is responsive in regard to Number  
11   2?

12          A.       Yes.

13          Q.       Number 3, "Any and all documents  
14   reviewed by you in preparation for this deposition."

15          A.       Yes, I have.

16          Q.       Okay. And, Doctor, I believe off the  
17   record we had discussed the fact that all you've  
18   brought with you today are literature that is in your  
19   reliance list and your expert reports; is that correct?

20          A.       Yes.

21          Q.       Okay. So you have not reviewed any  
22   documents in preparation for your deposition here today  
23   that were not in your reliance list?

24          A.       I mean, with the understanding that this

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1 is what I do for a living, there's a tremendous amount  
2 of stuff that I do read and review, in general, that's  
3 on the subject matter, but I believe that the stuff  
4 that's in my report is on the reliance list.

5 MR. SNELL: Just for clarification,  
6 counsel, are you asking about things he's  
7 reviewed since his report or depositions of  
8 plaintiffs' experts, things like that, because,  
9 obviously, those were not available to him at  
10 the pertinent time.

11 MR. SCHNIEDERS: I'm asking for anything  
12 at this point with Number 3 that he has  
13 reviewed in preparation for this deposition  
14 here today.

15 BY MR. SCHNIEDERS:

16 Q. Does that cover it, Doctor?

17 A. Essentially, yes. Understand that I  
18 also have access to information that is not published  
19 and that I am not at liberty to share because I'm an  
20 editor for journals and I review for -- so, obviously,  
21 I have not brought that, but I don't quote or cite that  
22 information in my report.

23 Q. Are you relying on any unpublished  
24 information --

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1           A.       I'm sorry. I'm not relying upon --  
2     sure, I'm not relying upon that information.

3           Q.       Okay. Did you review that information  
4     in preparation for your deposition here today?

5           A.       That is information that I have reviewed  
6     for my own role outside of this deposition, so not in  
7     preparation for this deposition.

8           Q.       Has your counsel been privy to those  
9     documents?

10          A.       He has not.

11                   MR. SNELL: I'm not his counsel.

12                   MR. SCHNIEDERS: I'm sorry.

13                   THE WITNESS: I'm sorry. Does that  
14     make -- is my intent clear with that?

15     BY MR. SCHNIEDERS:

16          Q.       Well, if we're going to be clear, I  
17     think what you're telling me is that you may have come  
18     about information outside of this litigation that has  
19     not informed your opinions in this litigation in any  
20     way, shape or form, correct?

21          A.       Correct.

22          Q.       And you're not relying upon that  
23     information to put forth your opinions in this case,  
24     correct?

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1 A. Yes, that's correct.

2 Q. So is it fair to say that whatever  
3 information this is you're talking about, you didn't  
4 review it in anticipation for this deposition?

5 A. Right.

6 Q. Did you review any depositions that are  
7 not on your reliance list?

8 A. Again, I've got the Ostergard  
9 deposition, which I only recently received, so I don't  
10 know if that would be on the list or not, but I did  
11 bring the deposition with me.

12 MR. SNELL: Since we're the ones who  
13 generated the list, it would not be on there,  
14 since the list was -- I took Ostergard's  
15 deposition, it was a week or two at least after  
16 he produced expert reports, so I do not think  
17 it's on there. I haven't even looked.

18 MR. SCHNIEDERS: Well, and I believe,  
19 counsel, did we receive a new reliance list  
20 yesterday.

21 MR. SNELL: It wasn't a new reliance  
22 list. It was, essentially, a corrected one. I  
23 think the paralegals attached his sling TVT  
24 reliance list to both his TVT report and his

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1 prolapse report, instead of attaching the right  
2 prolapse list to the prolapse report. So it's  
3 not amended or updated or anything like that.  
4 It's just they stuck the wrong one on the POP  
5 report.

6 MR. SCHNIEDERS: Okay. So the list that  
7 was produced yesterday was the list as of the  
8 date of the issuance of the report?

9 MR. SNELL: Like 29th to 30th of  
10 February.

11 MR. SCHNIEDERS: And did you bring a  
12 copy of that list that was produced yesterday  
13 because I don't know if I have that list to  
14 mark as an exhibit here today.

15 MR. SNELL: Do you have a copy?

16 THE WITNESS: This, POP?

17 MR. SNELL: If you want to take that,  
18 you can mark it.

19 MR. SCHNIEDERS: We'll get to that in a  
20 second.

21 MR. SNELL: But as to your question, I  
22 doubt Ostergard's deposition was on this, I  
23 don't see it on here.

24 BY MR. SCHNIEDERS:

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1 Q. Doctor, have you reviewed any documents  
2 since your deposition on the TVT report that you hadn't  
3 previously reviewed before the TVT report deposition?

4 MR. SNELL: Form.

5 THE WITNESS: Yes, the information as it  
6 relates to Gynemesh and Prolift were not part  
7 of my TVT report.

8 BY MR. SCHNIEDERS:

9 Q. But you issued those reports at the same  
10 time, didn't you?

11 A. No. This report was issued February 26,  
12 2016. The other report was issued back in October.

13 Q. Okay. Doctor, have you brought --  
14 strike that.

15 You haven't brought -- are there any  
16 photographs or other images including photographs of  
17 the plaintiffs, the plaintiffs' explanted mesh or  
18 products taken by you or for you which relate to your  
19 opinions in this case?

20 A. No.

21 Q. Have you brought any Ethicon products in  
22 your possession?

23 A. I don't have any Ethicon -- oh, Ethicon  
24 products, no.

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1           Q.        "Any and all documents, including time  
2    sheets, invoices, time records, billing records which  
3    record or document the work performed, time spent or  
4    charges made in connection with your expert opinion in  
5    this matter."

6           A.        I have my invoices, yes.

7           Q.        And are they here today?

8           A.        I'm sorry. What is the date of the last  
9    invoice? There should be a date end of February.

10          Q.        Yeah, there's a February 29th of this  
11   year.

12          A.        Right.

13          Q.        Is that the most recent invoice?

14          A.        Most recent invoice that I have  
15   submitted, correct.

16          Q.        Any communication between you and your  
17   counsel -- I'm sorry, strike that.

18               Any communication between you and counsel for  
19   the defendants, to the extent such communications  
20   relate to your compensation; identify facts or data  
21   that you were provided and that you considered in  
22   forming your opinions; or identify assumptions that  
23   plaintiffs' counsel provided you and that you relied on  
24   in forming your opinions.



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1 A. No.

2 Q. How have you communicated with defense  
3 counsel in this case?

4 A. By phone.

5 Q. Have you ever e-mailed with defense  
6 counsel?

7 A. Not an opinion or the stuff that you  
8 just referred to, no.

9 Q. So nothing about compensation rates or  
10 bill sheets or anything like that?

11 A. No.

12 Q. Did you collect a retainer in this case?

13 A. I did not.

14 Q. Do you typically collect retainers in  
15 cases in which you --

16 A. I do not.

17 Q. And if you let me finish my questions,  
18 I'll let you start off after that, if you don't mind,  
19 because otherwise we'll get on top of each other.

20 So, as I sit here, I've got two invoices that  
21 are dated January 31st of 2016 and February 29th of  
22 2016, and that is all of the time that you have billed  
23 to date in the Ethicon Gynecare mesh litigation titled  
24 MDL 200? I'm just reading off of this.

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1           A.       That is everything I have billed to  
2     date.

3           Q.       When were you first contacted to work in  
4     this case?

5           A.       End of August 2015.

6           Q.       All right. Moving through the notice to  
7     get through that, Number 10, any and all documents,  
8     including consulting agreements, time sheets, invoices,  
9     time records, billing records which record or document  
10    the work performed, time spent or charges made in  
11    connection with consulting related to studies,  
12    consulting work, cadaver labs, professional education  
13    training and any other work that has been compensated  
14    by defendants or expert fees charged to defendant  
15    related to any female pelvic mesh product sold by  
16    Ethicon for treatment of stress urinary incontinence or  
17    pelvic organ prolapse.

18           Did you bring any documents related to  
19    Number 10?

20                   MR. SNELL: I'll just note for the  
21                   record, I think we filed objections as to some  
22                   of these requests. Go ahead.

23                   THE WITNESS: I don't believe we've  
24                   provided any of that.

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1 BY MR. SCHNIEDERS:

2 Q. Have you provided any of that to defense  
3 counsel?

4 A. I don't have an independent recollection  
5 that I have.

6 Q. Whether you have provided it to defense  
7 counsel or not, do you have documents that would fall  
8 under category 10?

9 A. I don't have documents. If I'm not  
10 mistaken, at the TVT deposition we did cover the amount  
11 and extent of my participation and compensation from  
12 Ethicon.

13 Q. I appreciate that, Doctor, but as far as  
14 the documents that have been requested here at Number  
15 10, do you have any responsive documents in your  
16 possession?

17 A. Like I said, they were covered in the  
18 TVT deposition, that's all. That's all I have.

19 Q. You produced all the documents you had  
20 in your possession as part of the TVT deposition?

21 A. I don't recall the specifics, but I do  
22 recall that we went over all that on record, correct?

23 MR. SNELL: Yeah, I think he did produce  
24 whatever he had.

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1 THE WITNESS: Right.

2 MR. SNELL: I think this is the same as  
3 what he produced -- whatever he had, he  
4 produced.

5 THE WITNESS: Right, yes.

6 BY MR. SCHNIEDERS:

7 Q. So you produced consulting agreements?

8 A. I don't know the answer to that. I  
9 don't recall.

10 Q. Do you have consulting agreements with  
11 Ethicon?

12 A. None actively, no.

13 Q. Do you have the paper that reflects the  
14 consulting agreement with Ethicon?

15 A. No, I do not.

16 Q. You don't keep any of those for your  
17 files?

18 A. No.

19 Q. Do you keep records of your invoices  
20 that you send to Ethicon?

21 MR. SNELL: Object to form. Go ahead.

22 THE WITNESS: I don't have the records,  
23 no. I haven't done consulting with Ethicon in  
24 years, and I discard such things after usual

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1 tax, it might be five years, I can't remember,  
2 three to five years I discard them.

3 BY MR. SCHNIEDERS:

4 Q. Just so we're clear on the record, right  
5 now we're talking about things that are outside of  
6 litigation, correct?

7 A. Understood.

8 Q. And so when is the last time that you  
9 consulted outside of litigation with Ethicon?

10 MR. SNELL: Object. This is covered in  
11 his first deposition, but go ahead.

12 THE WITNESS: It's to the best of my  
13 recollection, and it is a guesstimate at best,  
14 2011. It's not been -- not in my working  
15 memory.

16 BY MR. SCHNIEDERS:

17 Q. Do you recall in the last six months  
18 destroying any of these kind of documents?

19 A. No, I did not.

20 Q. So is it your testimony here today that  
21 you have no documents that are responsive to Number 10  
22 in your possession that you have not previously  
23 produced as part of your TVT deposition?

24 A. Yes, it is.

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1 Q. Is that because the documents are all in  
2 the possession of your practice?

3 A. I don't believe they are.

4 Q. Okay. Well, if we go back, Doctor, and  
5 see from the TVT deposition that there wasn't anything  
6 produced that's responsive to Number 10 from you, are  
7 there responsive documents somewhere that you have?

8 A. I think I've answered that. I do not  
9 have what you're asking for in my possession, because I  
10 have not had any active consulting agreement with  
11 Ethicon for more than five years. I certainly have not  
12 destroyed anything since I was contacted by Mr. Snell  
13 regarding these matters.

14 Q. And you were contacted in August of  
15 2015?

16 A. I believe so.

17 THE WITNESS: Does that sound right to  
18 you?

19 MR. SNELL: I can't testify, but I think  
20 you're in the right ballpark.

21 THE WITNESS: Okay.

22 MR. SNELL: And this is to the best of  
23 your recollection.

24 THE WITNESS: To the best of my

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1 recollection.

2 BY MR. SCHNIEDERS:

3 Q. How were you contacted by Mr. Snell?

4 A. Telephone.

5 Q. Did you know Mr. Snell prior to that  
6 conversation?

7 A. No, I did not.

8 Q. Did you know any of Mr. Snell's partners  
9 prior to that?

10 A. No, I do not.

11 Q. Had you ever worked on a legal case  
12 prior to Mr. Snell contacting you?

13 MR. SNELL: Form.

14 THE WITNESS: I had worked on  
15 malpractice cases but not product liability  
16 cases.

17 BY MR. SCHNIEDERS:

18 Q. So you served as an expert witness in a  
19 medical malpractice case before?

20 A. I have.

21 Q. We'll talk about that in just one  
22 moment.

23 MR. SNELL: Counsel, this was all  
24 covered in depth in the TVT deposition.

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1 MR. SCHNIEDERS: Taking my deposition,  
2 Burt, you can talk about whatever you want.  
3 They're responsive questions.

4 MR. SNELL: Actually, no, you're not,  
5 because the parties have an agreement; there  
6 shall not be duplicative discovery of experts.

7 MR. SCHNIEDERS: I've looked through the  
8 entire transcript, and I'm very comfortable  
9 that I'm asking the right questions, not to  
10 mention the fact that you've given me a whole  
11 other reliance list that I got yesterday, so  
12 I've got to ask my questions and see what's out  
13 there. There weren't any consulting agreements  
14 produced as part of the TVT deposition.

15 MR. SNELL: I know that because he  
16 didn't have any, but I think he told you they  
17 were marked. They were definitely discussed in  
18 that deposition. I don't have the deposition  
19 with me, but I know for a fact that they were  
20 marked.

21 MR. SCHNIEDERS: Well, I just read it  
22 again last night so -- and those consulting  
23 agreements would have been there and, okay, you  
24 can look at what's been marked in there, if you



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1           have the transcript. There weren't any.

2                   MR. SNELL: I don't have the transcript  
3           with me.

4                   MR. SCHNIEDERS: Okay. Let's not waste  
5           time on it, all right.

6 BY MR. SCHNIEDERS:

7           Q.       Number 11, "Copies of Schedule C and  
8       Form 1099 of your tax records for the preceding five  
9       (5) tax years, as well as any other documentation that  
10      reflects consulting and/or expert fees charged to  
11      defendants (with personal information and any other  
12      information unrelated to consulting fees redacted)."

13                   MR. SNELL: We objected to that, and  
14           this witness will not be producing his tax  
15           forms.

16                   MR. SCHNIEDERS: And what's the basis of  
17           that objection?

18                   MR. SNELL: Invades his privacy, all the  
19           bases we set forth. Your experts have not  
20           produced any of their tax forms.

21 BY MR. SCHNIEDERS:

22           Q.       Number 12, "All correspondence,  
23       memoranda, e-mails and/or any other documentation  
24       reflecting communications (including written,

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1 electronic and/or oral) with any employees of  
2 defendants related to any female pelvic mesh product  
3 sold by Ethicon, Inc. for treatment of stress urinary  
4 incontinence or pelvic organ prolapse."

5 Have you produced any such correspondence,  
6 memoranda, e-mails or other documentation, Doctor?

7 A. I believe I answered earlier that I  
8 don't have any of those correspondence in my  
9 possession.

10 Q. What's your current e-mail address?

11 A. I think that's personal information.  
12 That's not a question I'm willing to answer on the  
13 record.

14 Q. Is it @ATT.net address?

15 A. I'm not going to answer that question.

16 Q. Is that on counsel's instruction or on  
17 your own volition?

18 A. I don't see how that's relevant to my  
19 role. I'm here to discuss my expert report and my  
20 opinions in that regard.

21 Q. In your communication with sales  
22 representatives for the defendant, did you ever use  
23 your personal e-mail address?

24 MR. SNELL: I'm going to object. This

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1 is irrelevant. This is, I think, covered in  
2 the first deposition, and you're about to get  
3 into areas that -- well, we'll leave it at  
4 that.

5 MR. SCHNIEDERS: I think I know what  
6 you're talking about, and I don't intend to go  
7 anywhere near that, so you can relax on that.

8 THE WITNESS: I'm not trying to be  
9 obstructive or difficult, but to the best of my  
10 knowledge, I don't recall ever using personal  
11 e-mail to respond -- well, I don't, I don't. I  
12 don't remember. I don't recall.

13 BY MR. SCHNIEDERS:

14 Q. I'll be fair to you on this, Doctor.  
15 I'm not trying to elicit some of what I think you're  
16 thinking I'm trying to elicit right now.

17 A. I understand.

18 Q. In your first deposition there were some  
19 e-mails where you did, and I'm not talking about any  
20 specific instance, but there were e-mails back and  
21 forth with other people that are involved in Ethicon in  
22 their professional capacity?

23 A. Correct, right, okay, correct. But I  
24 don't have in my possession any of that, those

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1 transcripts, I don't have any copies or -- I don't have  
2 copies of those e-mails. I haven't used an AT&T  
3 address in I don't know how long.

4 Q. And did -- with your new address which  
5 I've also seen on some e-mails, did you go back when  
6 you received this notice to review to see if you had  
7 any responsive e-mails?

8 A. I did not have any responsive e-mails.

9 Q. You looked for them?

10 A. Yes. The last -- I mean, the last  
11 communications I had with Ethicon had nothing to do  
12 with any of the stuff that we're discussing today.  
13 They were on projects that were unrelated to any of  
14 this.

15 Q. What projects?

16 A. They were projects for other products  
17 that are not related to Gynemesh or Prolift.

18 Q. Okay. They were other products that  
19 were made or in production or premarket by Ethicon?

20 A. They were concepts for potential  
21 products within this sphere of female pelvic floor  
22 disorders.

23 Q. Like the Sphinx?

24 A. Correct.

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1 Q. Any others?

2 A. No, no.

3 Q. And the Sphinx never made it to market,  
4 correct?

5 A. It never made it past the conceptual  
6 stage. Does that make sense to you?

7 Q. It does.

8 A. Okay.

9 Q. Number 13 is duplicative of some of the  
10 other ones. I'm assuming you are going to tell me that  
11 you have produced everything that is responsive to  
12 Number 13; is that correct, Doctor?

13 A. That would be my position, correct.

14 Q. Number 14, "All documents related to  
15 deponent's involvement with Ethicon's professional  
16 education, including, but not limited to any and all  
17 PowerPoints, course materials, outlines, videos or  
18 presentations, live surgical presentations, marketing  
19 evaluations created by or provided to deponent related  
20 to any female pelvic mesh product sold by Ethicon, Inc.  
21 for treatment of stress urinary incontinence or pelvic  
22 organ prolapse.

23 Do you have any responsive documents to Number  
24 14?

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1           A.       I do not have any of those items in my  
2     possession.

3           Q.       You didn't keep any PowerPoints or  
4     anything you put together?

5           A.       No. To be clear, I never created any of  
6     those talks. There were talks that might have been  
7     provided to me. Once my consulting arrangement changed  
8     and I threw things out, I don't really keep that stuff.

9           Q.       They were provided to you by Ethicon,  
10    right?

11          A.       Products related, right. I mean, I  
12    think some of them we have -- we have brought, the  
13    Prolift professional education materials. Nothing  
14    different than that.

15                 MR. SNELL: Right, but I think he's  
16                 asking you did you have -- do you have any from  
17                 back when you were a consultant, not stuff that  
18                 you reviewed and prepared that's on the thumb  
19                 drives.

20                 MR. SCHNIEDERS: Right.

21                 MR. SNELL: I think that's what he's  
22                 asking about.

23                 MR. SCHNIEDERS: That's correct.

24                 THE WITNESS: No, I don't have it.

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1 BY MR. SCHNIEDERS:

2 Q. Just so we're clear on the record here,  
3 Doctor, you've given talks on behalf of Ethicon, right?

4 A. Correct.

5 Q. You've used presentations in those talks  
6 at times like PowerPoints, right?

7 A. That were provided to me by Ethicon.

8 Q. And those were put together by Ethicon  
9 for you to present?

10 A. Correct.

11 Q. And you don't have any of those in your  
12 possession, as we sit here today, correct?

13 A. I do not.

14 Q. Okay. Number 15, "Any and all materials  
15 including, but not limited to, protocols, results,  
16 adverse events, minutes for study meeting related to  
17 any clinical trials and/or studies of any type related  
18 to deponent's work as consultant for defendant in any  
19 capacity related to any female pelvic mesh product sold  
20 by Ethicon, Inc. for treatment of stress urinary  
21 incontinence or pelvic organ prolapse."

22 Do you have any responsive documents, Doctor?

23 A. I do not.

24 Q. Are you currently involved in enrolling

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1 in a clinical trial?

2 A. I am not.

3 Q. So just so we're clear, anything that is  
4 responsive to Number 15 you've either produced or don't  
5 have anymore, correct?

6 A. Correct.

7 Q. "16. Any reports/documents, whether  
8 kept in hard copy or electronic form, relating to any  
9 other matter involving any female pelvic mesh product  
10 for treatment of stress urinary incontinence or pelvic  
11 organ prolapse."

12 Do you have any responsive documents to Number  
13 16, Doctor?

14 A. I do not.

15 Q. You don't keep anything on any other  
16 female pelvic products?

17 A. I do not.

18 Q. "Any and all documents, including  
19 transcripts or statements, between you and any  
20 governmental agency regarding any female pelvic mesh  
21 product used for treatment of stress urinary  
22 incontinence or pelvic organ prolapse."

23 Do you have any responsive documents to Number  
24 17, Doctor?



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1 A. I do not.

2 Q. Have you ever reported an adverse event  
3 to the FDA?

4 A. I have.

5 Q. Do you ever keep a record of that?

6 A. No.

7 Q. Have you ever reported an adverse event  
8 related an Ethicon product to the FDA?

9 A. I have.

10 Q. On how many occasions?

11 A. I don't know the answer to that.

12 Q. Ballpark, ten?

13 A. Ten may be a reasonable guess.

14 Q. Have you ever reported any adverse  
15 events to the FDA for any of the products we're here to  
16 talk about today?

17 A. I have.

18 Q. Can you tell me which products?

19 A. Prolift, I'd say three or five.

20 Q. Any for Gynemesh PS?

21 A. No.

22 Q. Any for TVT?

23 A. Not that I can specifically recall.

24 Hold on.

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1           In all honesty, most of the reports that I have  
2     filed with the MAUDE probably involved non-Ethicon  
3     products.

4           Q.       Any particular reason?

5           A.       I think that they reflect what -- these  
6     were not products that I personally had implanted, but  
7     they were women that I subsequently cared for, and it  
8     just simply reflects the nature of my referral  
9     practice.

10          Q.       Because as a physician, you have a duty  
11     when you find out about an adverse event to report it,  
12     regardless of how you come about that information,  
13     right?

14                   MR. SNELL:   Objection, calls for a legal  
15     conclusion.

16     BY MR. SCHNIEDERS:

17          Q.       Was that a yes, Doctor?

18          A.       I have reported events that I have come  
19     across as a surgeon.

20          Q.       And my point is just that regardless of  
21     whether or not it's your patient or you find out about  
22     it from another manner, you would still report an  
23     adverse event because you have a duty as a doctor to do  
24     that, correct?

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1 MR. SNELL: Objection, calls for legal  
2 conclusion.

3 THE WITNESS: I'm not so sure about the  
4 duty, but my personal practice is to report  
5 those events.

6 BY MR. SCHNIEDERS:

7 Q. And it's fair to say that with regard to  
8 types of mesh products that we're talking about here  
9 today, and I'm talking about the entire spectrum,  
10 regardless of Ethicon or other manufacturers, that  
11 you've reported more adverse events for the other  
12 manufacturers than Ethicon?

13 MR. SNELL: Form.

14 THE WITNESS: I would say that is likely  
15 true.

16 BY MR. SCHNIEDERS:

17 Q. Do you have any recollection of what  
18 product you've likely reported the most times as an  
19 adverse event?

20 A. I do.

21 Q. Which product is that?

22 A. I believe Apogee Perigee.

23 Q. Do you have any idea of how many adverse  
24 events you reported on that product?

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1 A. I do not.

2 Q. Number 18 says, "Any and all documents  
3 relating to an presentations, PowerPoints or lectures  
4 regarding any female pelvic mesh product used for  
5 treatment of stress urinary incontinence and pelvic  
6 organ prolapse."

7 Is your answer the same as it was regarding the  
8 materials themselves that you don't have anything in  
9 your possession?

10 A. That is correct.

11 Q. Lastly, Number 19, "Any demonstrative  
12 exhibits, such as graphics or charts, prepared by or on  
13 your behalf for use at trial."

14 Do you have any responsive documents?

15 A. We're talking about other than what has  
16 already been provided either in my TVT deposition or  
17 currently?

18 Q. Yes.

19 A. I have nothing in addition.

20 Q. You can set that to the side.

21 MR. SCHNIEDERS: I'm going to do a  
22 little housekeeping here because I actually  
23 premarked a few things, and I'm going to get  
24 off track if I don't do it the right way.

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1 (Document marked for identification as  
2 Toglia Deposition Exhibit No. 2.)

3 MR. SCHNIEDERS: I'm going to hand you  
4 your CV, which I've marked as Exhibit 2.

5 BY MR. SCHNIEDERS:

6 Q. Doctor, this looks like this was revised  
7 at the top right there on 8/13 of 2015; is that  
8 correct?

9 A. Yes.

10 Q. Is this your most current CV?

11 A. Yes.

12 Q. Doctor, you are what's called a  
13 urogynecologist, correct?

14 A. Actually, I am a specialist in female  
15 pelvic medicine and reconstructive surgery, which was  
16 formerly referred to as urogynecology.

17 Q. I see in 2013 that you went to get a  
18 board certification in female pelvic medicine and  
19 reconstructive surgery.

20 Can you tell me what that entailed?

21 A. I didn't go in 2013. I went in 2012 and  
22 in 2013 I received certification. So female pelvic  
23 medicine and reconstructive surgery is the fourth  
24 subspecialty within the specialty of obstetrics and

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1     gynecology. It is duly accredited by both the American  
2     Board of Obstetrics and Gynecology and the American  
3     Urologic Board.

4             This involved -- this is a multipart process  
5     culminating in taking and passing a written exam.  
6     Prior to that, there were demonstration of adequate  
7     case volume and level of training. For example, you  
8     had to be previously board certified either by the  
9     American Board of OB-GYN in OB-GYN or the American --  
10    the ABU, the American Board of Urology.

11            Q.     And was that a facility locally that you  
12    were able to go and do some of this work, or how did  
13    that actually work out?

14            A.     Well, the process is guided by the  
15    ACGME, the American College of Graduate Medical  
16    Education. The exam itself was taken via computer by  
17    local sites throughout the country, locally through  
18    some of the different learning centers.

19            Q.     Prior to 2013 when you received the  
20    board certification and began your work, did you  
21    consider yourself to be a specialist in the area of  
22    female pelvic medicine and reconstructive surgery?

23            A.     That's correct.

24            Q.     How many people nationwide hold this

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1 subspecialty, if you know?

2 A. So in 2013 approximately 750 of us were  
3 board certified, and 2014/2015 there might have been  
4 the addition of another 100 or so each year. I  
5 couldn't give you the final number. I'm sure it's  
6 something that's readily available, but I'm going to  
7 guesstimate we're talking about 1,200 individuals who  
8 are currently board certified in the subspecialty.

9 Many others, including some of your experts,  
10 did not sit for the boards, but this is still their  
11 area of expertise and practice.

12 Q. Did any pharmaceutical company or device  
13 company in any way, shape or form fund or help with  
14 your board certification?

15 A. No, none whatsoever.

16 Q. They didn't sponsor any programs that  
17 had to do with it?

18 A. No.

19 Q. Do you have any academic appointments,  
20 Doctor?

21 A. I do. They're listed on my CV.

22 Q. And when I say that, are you employed by  
23 any of these facilities?

24 A. I am not.

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1 Q. Do you teach any classes?

2 A. I teach clinically, I give lectures. I  
3 don't teach classes in the sense that a college  
4 professor would teach classes.

5 Q. On Page 2 and, obviously, you know your  
6 CV so you probably don't need it to talk through it,  
7 but I see that you're a member currently of some  
8 professional societies. I think I know which ones they  
9 are, but there was a couple typos later on, so I just  
10 want to make clear which of these professional  
11 societies are you currently a member of?

12 A. Sure. I'm currently a member of the  
13 American Urogynecologic Society, the Society for  
14 Gynecologic Surgeons, the International Urogynecology  
15 Society, which is not on this list, I don't think. I'm  
16 a fellow of the American College of Obstetrics and  
17 Gynecology as well.

18 Q. Okay. And moving to the next page, it  
19 appears that you hold or at least held as of 2015 a  
20 vice chair position for the Committee for Government  
21 Relations and Coding at the American Urogynecologic  
22 Society; is that correct?

23 A. I'm currently the chair of that  
24 committee.



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1 Q. Okay.

2 A. And it's actually the chair of coding.

3 Q. Okay. And in your position as vice  
4 chair and now chair, what are your duties?

5 A. I represent the society nationally at  
6 meetings such as the CPT, the RUC. I interact directly  
7 with the government through CMS. I represent the  
8 society as a liaison member to the American College of  
9 Obstetrics and Gynecology, and I either head or direct  
10 certain task forces as they relate to coding and health  
11 economics within the sphere of female pelvic medicine.

12 Q. Okay. And if I say AUGS, you know what  
13 I'm talking about, right?

14 A. I do.

15 Q. So your position as vice chair, then  
16 chair of this committee with AUGS is tied to this  
17 bottom one here, where it says "Member, ACOG Committee  
18 of Health Economics and Coding, AUGS Liaison"?

19 A. Yes.

20 Q. Okay. Tell me what AUGS is.

21 A. AUGS is a professional organization of  
22 healthcare providers, which includes physicians,  
23 physical therapists, nurse specialists that are  
24 interested in promoting excellence in female pelvic

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1 medicine and reconstructive surgery.

2 Q. Is it sponsored by any pharmaceutical or  
3 device companies?

4 A. It is not.

5 Q. What about ACOG, tell me what ACOG is.

6 A. ACOG is the professional organization,  
7 it's the American College and Congress of Obstetrics  
8 and Gynecology that is based out of Washington, DC and  
9 comprises the professional members, again, doctors,  
10 nurse practitioners, other healthcare providers in the  
11 specialty of obstetrics and gynecology.

12 Q. Okay. And is ACOG sponsored or funded  
13 by any pharmaceutical or device companies?

14 A. No.

15 Q. And you're sure about that with regard  
16 to AUGS and ACOG?

17 A. I am certain about that.

18 Q. Down here under Hospital Service it  
19 says, "System Chief, Division of Female Pelvic Medicine  
20 and Reconstructive Pelvic Surgery, Main Line Health."

21 What is Main Line Health?

22 A. Main Line Health is the largest health  
23 system here in Philadelphia. It's a not-for-profit  
24 system consisting of four hospitals.

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1 Q. And do you have privileges at all four  
2 of those hospitals?

3 A. I have privileges at all four hospitals.

4 Q. Is there any particular hospital you do  
5 the majority of your procedures at?

6 A. Yes.

7 Q. Which one is that?

8 A. I split my time clinically between Paoli  
9 Hospital located in Paoli, Pennsylvania and Riddle  
10 Hospital located in Media, Pennsylvania.

11 Q. If you want to move on, Doctor, to Page  
12 4, there is a section at the bottom there that's called  
13 "Past Clinical Research Projects."

14 Do you see that?

15 A. I do.

16 Q. And it looks to me as if there are nine  
17 times in your past in which you've participated in a  
18 clinical study; is that correct?

19 MR. SNELL: Hold on. Did you say nine?

20 MR. SCHNIEDERS: That's what I see,  
21 because I'm skipping ten, so I'm going to ask  
22 him separately.

23 MR. SNELL: I'm going to object to form.

24 BY MR. SCHNIEDERS:

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1           Q.       You tell me, because ten seems to be a  
2     bit different, because I asked you earlier if you were  
3     in the process of enrolling patients, and you told me  
4     no. So let's just start with 1 through 9. It looks  
5     like there were several clinical research projects you  
6     were involved with?

7                   MR. SNELL: I'll just note for the  
8                   record this issue in Number 10 and the  
9                   statement about currently enrolling patients I  
10                  know was covered in his prior deposition.

11                  MR. SCHNIEDERS: I'll let you make your  
12                  objections. If I can finish my questions  
13                  before you start them, if you don't mind.

14                  MR. SNELL: Go ahead. Covered.

15     BY MR. SCHNIEDERS:

16           Q.       So, Doctor --

17           A.       I've participated in ten, and I am not  
18     currently enrolling.

19           Q.       Okay. And tell me why that is?

20           A.       Because this is simply a typographical  
21     error, and that was covered in my deposition with the  
22     TVT trial. And my apologies, the problem is I can't  
23     make corrections because these belong to the Court. If  
24     I had another copy, I'm happy to correct that for the

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1 next time, but I realize this comes up, but I don't  
2 have my own set of private things that I can correct  
3 these things on, but I will tell you that that is an  
4 old trial that has already been published.

5 Q. And that's my question, Number 10 then,  
6 is that the actual trial that you did go on to publish?

7 A. Yes.

8 Q. That's listed as Number 23 under your  
9 publications?

10 A. Yes.

11 Q. Doctor, other than 23, are there any  
12 publications that you have ever made with regard to any  
13 mesh product?

14 MR. SNELL: Form.

15 THE WITNESS: Twenty-four is an  
16 editorial that I wrote that talked about  
17 sacrocolpopexy, which would involve the mesh,  
18 but that is an editorial.

19 BY MR. SCHNIEDERS:

20 Q. But no other articles other than those  
21 two?

22 A. Article 16 was a study I published with  
23 my own patient population. Some of those patients did  
24 have a mesh procedure, although, to the best of my

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1 knowledge, we did not stipulate what that was.

2 Q. But fair to say that that article was  
3 primarily about polyester sutures?

4 MR. SNELL: Form.

5 THE WITNESS: As the title suggests, it  
6 was about both long-term surgical outcomes as  
7 well as wound complications in that population.

8 BY MR. SCHNIEDERS:

9 Q. All right, Doctor, I'd like to switch  
10 topics now, and I'd like to start with your first work  
11 with Ethicon.

12 It's my understanding that you were recruited  
13 by Dr. Lucente; is that correct?

14 MR. SNELL: Objection, asked, and this  
15 is all covered in his first deposition.

16 THE WITNESS: No, I was not recruited by  
17 Dr. Lucente.

18 BY MR. SCHNIEDERS:

19 Q. Well, how would you characterize it?

20 MR. SNELL: Objection, asked and  
21 answered, prior covered.

22 THE WITNESS: How I was contacted by  
23 Ethicon?

24 BY MR. SCHNIEDERS:

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1 Q. Yes.

2 A. I don't recall the specifics. I would  
3 have been contacted probably by a product manager.

4 Q. Approximately what year would that have  
5 been?

6 MR. SNELL: Same objection. This is all  
7 covered in the prior deposition.

8 THE WITNESS: 1999.

9 BY MR. SCHNIEDERS:

10 Q. Okay. Had you ever worked for Ethicon  
11 prior to being contacted for that consulting?

12 A. That was the first contact.

13 Q. Okay. Prior to 1999 had you worked with  
14 other pharmaceutical or device companies?

15 A. I think I had, yes.

16 Q. Which companies had you worked with  
17 prior to working with Ethicon?

18 A. Well, I did clinical trials for what we  
19 then called Yamanouchi, which is now called Astellas.  
20 I did a clinical trial with Eli Lilly, a clinical trial  
21 with Pfizer.

22 Q. Pharmacia?

23 A. I did some work with Johnson & Johnson,  
24 which owns Ethicon, but at the time it was not with

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1 Ethicon, I don't believe, no. Realize this is not  
2 directly relevant, but whether or not Monistat as a  
3 product was Ethicon versus Johnson & Johnson, I don't  
4 know.

5 Q. But that was the product at that time?

6 A. Correct.

7 Q. Aside from what's listed in your past  
8 clinical research projects and the companies that  
9 you've listed as the sponsors, do you recall any other  
10 pharmaceutical companies you worked with prior to 1999?

11 A. Yes, there were a host of them.

12 Q. Which ones can you name for me?

13 A. Now you're really taxing my long-term  
14 memory. Rhone-Poulenc Rorer. As you probably are  
15 aware, counselor, many of these companies have been  
16 absorbed and renamed.

17 Q. That is Aventis now, that would be  
18 Aventis?

19 A. Right, correct. Pharmacia Upjohn,  
20 that's probably it.

21 Q. Other than the ones that are listed in  
22 your CV, that would be about it?

23 A. Correct.

24 Q. Okay. Starting in 1999, what was your



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1 work with Ethicon?

2 MR. SNELL: Objection, form and covered  
3 in prior dep.

4 THE WITNESS: I think I previously  
5 stated that initially I may have participated  
6 in some kind of market research that actually  
7 probably was prior to '99, let's say '98. I  
8 don't necessarily consider that a consulting  
9 relationship. I was just asked to give  
10 feedback from a marketing perspective on the  
11 TVT product. At some point in time, I started  
12 to get involved more in the professional  
13 education teaching, the TVT technique.

14 Does that answer your question?

15 BY MR. SCHNIEDERS:

16 Q. Sure, that's the beginning. So as a  
17 preceptor, correct?

18 A. Correct. And I also started to serve in  
19 an advisory or a consultant role.

20 Q. What products did you serve as a  
21 preceptor for with Ethicon?

22 A. I would say the TVT family of products,  
23 TVT, TVT obturator, TVT Secur, TVT Abbrevio, TVT Exact.

24 Q. Did you ever serve as a preceptor for

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1 Gynemesh PS?

2 A. To the best of my knowledge, no.

3 Q. Same question with regard to Prolift?

4 A. Yes.

5 Q. Have you ever served as a preceptor for  
6 any company that was not Ethicon?

7 A. I don't believe so.

8 Q. So your relationship with Ethicon would  
9 have began with a market research consulting or  
10 whatever you want to call that in 1998 and, based upon  
11 your recollection, continued till about 2011?

12 MR. SNELL: Object to form, previously  
13 covered.

14 THE WITNESS: I believe so, yes.

15 MR. SCHNIEDERS: I'm going to switch  
16 topics. Does anyone want to take a break, or  
17 are we okay?

18 MR. SNELL: Take a five-minute break.

19 (Brief recess taken at 2:09 p.m.)

20 (Deposition resumes at 2:14 p.m.)

21 BY MR. SCHNIEDERS:

22 Q. Doctor, we're back after a short break.

23 In your current practice, Doctor, what  
24 surgeries do you perform for stress urinary

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1 incontinence?

2 A. Currently, we perform a combination of  
3 midurethral slings, such as TVT Exact, TVT Abbrevio. We  
4 perform periurethral bulking procedures, autologous  
5 fascial slings, retropubic urethropexies.

6 Q. And are there any slings that you use  
7 aside from TVT products?

8 A. There are not.

9 Q. Have you ever used any sling aside from  
10 a TVT product?

11 MR. SNELL: Objection.

12 BY MR. SCHNIEDERS:

13 Q. Strike that. Have you ever used any  
14 sling aside from an Ethicon product?

15 MR. SNELL: Form, previously covered.

16 THE WITNESS: Yes.

17 BY MR. SCHNIEDERS:

18 Q. What products have you used in addition?

19 A. Boston Scientific, Advantage Fit, AMS  
20 RetroArc. Cook had a biologic sling, Surgisis ST,  
21 don't quote me on the trade name on that one. I think  
22 that's it.

23 Q. Fair to say the vast majority of the  
24 slings that you've put in have been TVTs?

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1 A. I would say 99%.

2 Q. What nonsurgical remedies are you using  
3 for women suffering from stress urinary incontinence  
4 currently?

5 A. Currently, we use biofeedback,  
6 electrical stimulation, pelvic floor muscle therapy.  
7 We actually have a physical therapist within the  
8 practice for that. Previously, as you can see from my  
9 CV, we were involved in the Duloxetine trial.  
10 Occasionally, we will use barrier type devices.

11 Q. When a woman comes into your office with  
12 stress urinary incontinence, what's your first line  
13 treatment?

14 A. Well, first line treatment starts with  
15 education, pelvic floor muscle exercises, behavioral  
16 modification, fluid management.

17 Q. What current surgeries do you use for  
18 pelvic organ prolapse?

19 A. Again, this is what I do for a living.  
20 There's a wide breadth of procedures that we do either  
21 abdominal, vaginal, with or without hysterectomy,  
22 native tissue plications, graft augmentation,  
23 specifically abdominal sacrocolpopexies, obliterative  
24 procedures such as colpocleisis,

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1 c-o-l-p-o-c-l-e-i-s-i-s.

2 Q. What nonsurgical remedies do you use?

3 A. Again, we will use physical therapy,  
4 pelvic floor muscle rehabilitation, pessaries.

5 Q. Do you currently use the Gynemesh PS?

6 A. I do.

7 Q. How often would you say you currently  
8 use the Gynemesh PS?

9 A. Two days a week.

10 Q. And is that two surgeries a week, or is  
11 that on two days you use it several times?

12 A. Two days a week I typically do between  
13 six and eight surgical procedures a week for  
14 incontinence or prolapse.

15 Q. Okay. And specific to Gynemesh PS, how  
16 often are you using that?

17 A. I use it two days a week, as I  
18 mentioned, perhaps maybe half my surgical repairs,  
19 maybe 40%.

20 Q. 40% of surgical repairs of POP?

21 A. For prolapse. It varies obviously.

22 Q. How many pelvic organ prolapse surgeries  
23 would you estimate you have performed as a surgeon?

24 A. Thousands. I've been in practice for

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1 nearly 25 years. I have an annual surgical load that  
2 varies probably between 150 and 200 surgical procedures  
3 a year.

4 Q. And how many times do you believe or  
5 would you estimate that you used Gynemesh PS for the  
6 surgery?

7 A. I believe that's in my surgical --  
8 excuse me. I believe that's in my report. Off the top  
9 of my -- I just want to verify it. Off the top of my  
10 head, I believe it was 3,000, approximately 3,000  
11 within our practices.

12 Q. And that's specific to Gynemesh PS?

13 A. I believe so. I mean, it's Gynemesh and  
14 related materials.

15 Q. Well, I'm going to ask, so how many  
16 Prolifts?

17 A. Prolifts probably number 200 or more.

18 Q. You say "and related materials," are you  
19 including the Prolift within that 3,000 for Gynemesh?

20 A. I'm sorry, let me try to be more clear.  
21 I'm talking about specifically macroporous  
22 polypropylene graft material, which would include  
23 Gynemesh PS, Prolift predominantly.

24 Q. Can you explain how that mesh differs

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1 from the TVT mesh?

2 MR. SNELL: Form.

3 THE WITNESS: Yes, I mean, they're both  
4 type 1 polypropylene mesh. I believe I covered  
5 this in my report. There are differences in  
6 terms of both weight and pore size.

7 BY MR. SCHNIEDERS:

8 Q. And what are the differences in weight  
9 and pore size?

10 A. Again, I believe I've covered that in my  
11 reports. Approximately, Gynemesh PS is going to be  
12 about 42, 43 grams per meter squared. It's got a pore  
13 size of about 2,400 microns.

14 The mesh used for TVT is approximately twice  
15 that. I believe the mesh is probably in the  
16 neighborhood of 90 grams per meter squared. The pore  
17 size is probably around 1,200 microns.

18 Q. You said 2,400 microns for Gynemesh?

19 A. 2.4 millimeters is the pore size.

20 Q. Doctor, do you keep track of any  
21 complications you have with your mesh surgeries?

22 A. Yes.

23 MR. SNELL: Form, asked and answered  
24 earlier.

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1 BY MR. SCHNIEDERS:

2 Q. How do you keep track of that?

3 MR. SNELL: Same objection.

4 THE WITNESS: Are you allowing me to  
5 answer?

6 MR. SNELL: You can go ahead and answer.  
7 I mean, it's all in the report.

8 THE WITNESS: It's changed throughout  
9 the years. Currently, our patients are  
10 enrolled in a national registry prospectively,  
11 where we keep track of all prolapse surgery.

12 Previously, we would use private  
13 databases. Obviously, we have medical records  
14 in our office. We have electronic health  
15 records in our system. I've been in the same  
16 practice now for 19 years.

17 BY MR. SCHNIEDERS:

18 Q. Okay. And you keep track of all those  
19 numbers?

20 A. The records are all available to us. We  
21 review them periodically as we go on.

22 Q. When you say "periodically," who are  
23 "we"?

24 A. I guess you're looking at we. We would



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1 be me. It would be me, my partners.

2 Q. How many partners do you have?

3 A. I currently have one physician partner  
4 and one nurse practitioner partner.

5 Q. And does your nurse -- or I'm sorry,  
6 your physician partner, does she review those along  
7 with you?

8 A. My current partner who has been with me  
9 less than two years has not. My previous partner had.

10 Q. And when you review the data that you  
11 have in your office regarding how many you've put in,  
12 what kind of report, if anything, do you output as a  
13 result of that?

14 A. It depends. I'll offer as an example,  
15 you know, my partner at the time Dr. Fagan and I  
16 published the article that we spoke of earlier, in  
17 which we, from the database, reviewed nearly 100 women  
18 that had undergone prolapse surgery using a specific  
19 technique sacrospinous ligament suspension, and we  
20 looked at outcomes, we looked at complications,  
21 recurrences, re-operations. So temporally we may stop  
22 and look at what we've been doing to better understand  
23 what the limitations and successes are of those  
24 procedures.

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1 Q. Okay. And do you reduce what you look  
2 at to any sort of a tangible form that you can share  
3 with the company or other physicians?

4 MR. SNELL: Object to form.

5 THE WITNESS: I wouldn't share anything  
6 with a company. It has nothing to do with a  
7 company. It varies. Sometimes we review it  
8 internally and we do nothing with it.  
9 Sometimes we publish it, sometimes we present  
10 it. Sometimes this is done as part of a larger  
11 consortium of researches, such as the TVT  
12 Secur. Obviously, the prospective registry  
13 database is something that we contribute to. I  
14 guess in that regard my current partner and I  
15 contribute to that database together. Someone  
16 else is analyzing that, so it just varies.

17 BY MR. SCHNIEDERS:

18 Q. Do you keep track of complications as a  
19 result of your database?

20 A. Yes.

21 Q. And do you review those periodically as  
22 well?

23 A. Yes.

24 Q. When is the last time you looked at

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1 that?

2 A. Yesterday.

3 Q. Forgive me, Doctor, but when you look at  
4 this, what are you looking for? Are you just looking  
5 at straight numbers? What is it that you're seeing?

6 A. It depends upon the clinical question  
7 that at the time we're interested in looking at. It's,  
8 you know, currently we've been looking at voiding  
9 function following midurethral slings in our patients,  
10 how they are at, say, one month. You know, we'll look  
11 at our rates of retention, need for revision, things  
12 like that.

13 Q. Do you have a number of women that  
14 needed revisions that you implanted mesh in?

15 MR. SNELL: Form.

16 THE WITNESS: It's a very, very small  
17 number.

18 BY MR. SCHNIEDERS:

19 Q. Well, let me ask you this, Doctor: Can  
20 you tell me how many revisions you've performed in your  
21 career?

22 MR. SNELL: Object. I think this was  
23 covered in prior depo.

24 THE WITNESS: It was.

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1 MR. SNELL: You can go ahead and answer  
2 the question. Let me try and pull up the  
3 transcript.

4 THE WITNESS: I don't have that in my  
5 working fund of knowledge. It's essentially on  
6 an annual basis and, again, understand that  
7 more the revisions that I do are not patients  
8 that I was the planter so -- but it's about 1  
9 to 2%.

10 BY MR. SCHNIEDERS:

11 Q. One to 2% of your --

12 A. Of those I implant, correct.

13 Q. And I've seen you testify on this  
14 particular issue before, and you stated that it's your  
15 belief that it's physician error when there's a  
16 complication; is that correct?

17 MR. SNELL: I'm going to have to object.  
18 I think you may have misstated his testimony.

19 MR. SCHNIEDERS: Well, he can certainly  
20 tell me that, if that's the case.

21 MR. SNELL: -- in its entirety. Why  
22 don't you show it to him then, because I don't  
23 know what you're talking about, to be honest  
24 with you.

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1 MR. SCHNIEDERS: I'm asking him a  
2 question. If he says I'm not stating it right,  
3 then please do, Doctor. I'll ask the question  
4 again.

5 THE WITNESS: You're asking me a  
6 question, and I'm more than happy to answer,  
7 but you're not providing me with the foundation  
8 or the reference.

9 BY MR. SCHNIEDERS:

10 Q. Okay. Let me ask it this way: Do you  
11 believe that when there is a mesh complication that it  
12 is the result of physician error?

13 MR. SNELL: Form, overbroad.

14 Are you talking sling, prolapse or  
15 anything?

16 MR. SCHNIEDERS: I'm asking a question.

17 MR. SNELL: So overbroad.

18 THE WITNESS: Would you be okay with  
19 substituting operator dependent for physician  
20 error? I don't know that I'm not comfortable  
21 with the term "physician error." I mean, I  
22 think it's operator dependent, rather than  
23 material related.

24 BY MR. SCHNIEDERS:

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1 Q. Okay. That's fair.

2 So to put it in simpler terms, it's the result  
3 of something that was or was not done by the physician,  
4 not saying it was negligent or anything like that?

5 A. I understand.

6 Q. That was the variable, not the material,  
7 correct?

8 MR. SNELL: Same objection, overbroad.

9 THE WITNESS: So --

10 MR. SNELL: Vague as to time and scope.  
11 Go ahead.

12 THE WITNESS: So the background is  
13 simply, you know, you've got the surgeon,  
14 you've got the patient, and the patient  
15 certainly -- the risks for something like  
16 retention varies based upon the patient and  
17 related co-morbidities. Understand that pelvic  
18 floor disorders rarely exist in isolation;  
19 therefore, you can have stress leakage, you can  
20 also have bladder dysfunction, voiding  
21 difficulty. So -- and you can have stress  
22 leakage and prolapse. You can have stress  
23 leakage, prolapse and voiding dysfunction. You  
24 can have all three of them with pre-existing

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1           neurologic conditions, like Parkinson's,  
2           multiple sclerosis, diabetes.

3                       So understanding that you've got  
4           operator variables and then you have patient  
5           variables as well, and then you have  
6           technique-related specifics. So they can be  
7           any combination, you know, of the above. Most  
8           of them, in my experience and in my extensive  
9           review of the literature, relate to the ones  
10          other than the material itself.

11       BY MR. SCHNIEDERS:

12               Q.       And is it your opinion, Doctor, that  
13       with regard to the Ethicon products that you are  
14       testifying as an expert in this litigation, that those  
15       products do not cause mesh complications?

16                       MR. SNELL: Form. Same objections as  
17       before.

18                       THE WITNESS: There are complications  
19       related to Gynemesh and prolapse, such as  
20       erosion, that obviously it's the material that  
21       has eroded, but it is my opinion, as stated in  
22       my report, that this is not inherent in the  
23       material itself.

24       BY MR. SCHNIEDERS:

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1 Q. Okay. And explain that for me.

2 A. Sure. I think I have explained it in my  
3 report quite extensively that, first of all, all  
4 patients who have prolapse have deficient tissue,  
5 nonfunctioning muscle and pre-existing issues that any  
6 of the surgical techniques that we employ in prolapse  
7 surgery come with inherent risks, and I think the  
8 literature is quite clear across thousands of studies  
9 involving tens of thousands of women that risks are  
10 related to surgery as a broad category and not  
11 specifically the Prolift or Gynemesh procedure. It's  
12 quite clear to me that it's very similar and sometimes  
13 lower than the baseline risk of surgery.

14 Q. So in those women, erosion would have  
15 occurred no matter what you put in them, right?

16 MR. SNELL: Objection, form.

17 THE WITNESS: With the understanding  
18 that most prolapse surgeries involve either  
19 suture or synthetic grafts or biological grafts  
20 or combinations thereof, complications such as  
21 wound complications, I'll take mesh erosion is  
22 simply one type of wound complication, the  
23 complications occur equally whether it's  
24 sutures or biologic grafts or synthetic grafts,



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1           and I think the literature more than adequately  
2           supports that position.

3   BY MR. SCHNIEDERS:

4           Q.       Doctor, when I say mesh complications,  
5   what does that mean?

6                   MR. SNELL:   Form, calls for speculation.

7                   THE WITNESS:   I don't know what you mean  
8           by that.

9   BY MR. SCHNIEDERS:

10          Q.       What does it mean to you?

11          A.       What does mesh complications mean to me?  
12   I guess literally it means any adverse event that may  
13   be associated with mesh.

14          Q.       And what adverse events, in your mind,  
15   may be associated with mesh?

16          A.       Again, counselor, maybe I didn't make  
17   myself clear, given that it is impossible to separate  
18   out the other variables, operator dependent variables,  
19   patient related risk factors, general techniques  
20   regarding prolapse surgery, the risks seem to be  
21   similar across the board and independent of the  
22   specific techniques.

23          Q.       So when I asked you what mesh  
24   complication meant to you, you said it meant any

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1 adverse event that may be associated with mesh,  
2 correct?

3 A. Yes, I'm just interpreting what you  
4 asked me.

5 Q. That's what you said, those were your  
6 words, right?

7 A. Those were my words.

8 Q. Okay. And when I ask you what adverse  
9 events might be associated with mesh, your answer is  
10 there are none?

11 A. That's not what I said, counselor. I  
12 gave you my answer.

13 (Document marked for identification as  
14 Toggia Deposition Exhibit No. 3.)

15 BY MR. SCHNIEDERS:

16 Q. I'm going to show you what I've marked  
17 as Exhibit 3, which is a copy of your website's front  
18 page. It's several pages long because if you go on the  
19 right side of the second page, you'll see there's a  
20 section entitled "Questions About Vaginal Mesh?"

21 Do you see that?

22 A. I do.

23 Q. Who wrote that?

24 A. I would say I was probably the author of

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1 that.

2 Q. Okay. And at the very beginning there,  
3 it's got a link to the position statement from  
4 AUGS/SUFU, correct?

5 A. Correct.

6 Q. But what I want to go to is down the  
7 second to last page, and just so everybody is aware,  
8 and you know this, Doctor, everybody else in this room  
9 might not, but there's a section where you click for  
10 more, and that's where the rest of this language comes  
11 from.

12 Does that seem familiar with your website,  
13 Doctor?

14 A. Correct.

15 Q. So that's why it's several pages longer  
16 than the rest of it.

17 But if you go to the last page that has words  
18 on it, in the second to last paragraph it says,  
19 "Urogynecology Associates maintains a large patient  
20 database of women in whom we have performed these  
21 procedures, and we are continually reviewing our  
22 results. Our physicians have been involved in clinical  
23 research in this area, and, in general, our data  
24 suggests a largely positive experience and high patient

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1 satisfaction."

2 Do you see that?

3 A. I do.

4 Q. This database, is that what you are  
5 discussing when you say that you review these things on  
6 a regular basis?

7 A. Yes.

8 Q. And did you think about putting your  
9 data into a form that you might be able to bring here  
10 today in order to support your opinions?

11 A. No.

12 Q. Why not?

13 MR. SNELL: I'm going to object. I  
14 don't think it's actually called for, but go  
15 ahead.

16 THE WITNESS: You know, I don't think  
17 that that would be something that would be --  
18 it's not something I could easily put together,  
19 you know, quickly.

20 BY MR. SCHNIEDERS:

21 Q. But you are able to look at it and tell  
22 patients that are coming into your office that the data  
23 suggests a largely positive experience and high patient  
24 satisfaction?

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1 A. That is correct.

2 Q. And going on to the last paragraph right  
3 here it says, finally, our physicians -- just so we're  
4 clear, Doctor, it's you and one other partner right  
5 now, correct?

6 A. That's correct.

7 Q. "Finally, our physicians have extensive  
8 experience in the evaluation and management of women  
9 who have experienced complications from transvaginal  
10 mesh procedures, including the surgical revision or  
11 removal of such devices."

12 Do you see that?

13 A. I do.

14 Q. When you say "complications from  
15 transvaginal mesh procedures," what do you mean when  
16 you write that?

17 A. I mean that if a women previously  
18 underwent a transvaginal mesh procedure or really any  
19 kind of surgery for pelvic organ prolapse or  
20 incontinence, whether it involved sutures or mesh  
21 material, that we have experience in evaluating and  
22 treating those conditions.

23 Q. So, as it sits here today with regard to  
24 the Ethicon products that you are opining about, the

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1 products themselves don't cause the complications, it's  
2 some mixture of the patient, the doctor and potentially  
3 some other variable, correct?

4 MR. SNELL: Form.

5 THE WITNESS: It's a combination of all  
6 those things. I mean, if you do surgery  
7 without suture, you can't have suture-related  
8 problems. If you do surgery with suture, if  
9 it's permanent suture, you know, you can have  
10 mesh -- excuse me -- you can have suture  
11 related complications or adverse consequences,  
12 as I've previously published. And if you do  
13 procedures with biological grafts or synthetic  
14 mesh materials, there is a, you know, baseline  
15 risk as it is laid out in our report of, you  
16 know, percentages of patients that might  
17 experience exposure of the material.

18 BY MR. SCHNIEDERS:

19 Q. If a woman came in to your office and  
20 had previously had a Ethicon product, whether it be  
21 Gynemesh PS or Prolift or TVT and they had a  
22 complication, immediately you would understand that it  
23 wasn't that product that caused the complication,  
24 correct?

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1 MR. SNELL: Objection, form, incomplete  
2 hypothetical, vague.

3 THE WITNESS: I'm not sure that I  
4 understand the foundation. If somebody had a  
5 Prolift procedure and comes to my office with  
6 exposed mesh, it's going to be my assumption  
7 that it is the Prolift mesh that is what I'm  
8 seeing in the vagina.

9 BY MR. SCHNIEDERS:

10 Q. But it would be your assumption that the  
11 Prolift mesh didn't cause the problem, correct?

12 MR. SNELL: Objection, same objection.

13 THE WITNESS: Wound complications are  
14 caused by problems with wound healing.

15 BY MR. SCHNIEDERS:

16 Q. Not the mesh, correct?

17 A. Not the mesh, correct.

18 Q. Okay. Would your opinion be the same if  
19 it was a Boston Scientific product?

20 A. Yes.

21 Q. So you don't believe that Boston  
22 Scientific products can cause complications, the mesh  
23 itself?

24 MR. SNELL: Form, overbroad.

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1 THE WITNESS: I think complications can  
2 occur in people who have undergone implantation  
3 with these materials. I think that the opinion  
4 that I have expressed in my report is that  
5 these are known complications that occur with  
6 all of our surgeries to similar degrees.

7 BY MR. SCHNIEDERS:

8 Q. And I guess that's my question. You're  
9 saying that these are known complications that can  
10 occur with these products, but you're saying that  
11 across the board it's not the product causing the  
12 complication, correct?

13 A. It is not the product causing the  
14 complication, correct.

15 Q. It's something else, it's a variable of  
16 either the physician, the patient or some combination  
17 of those two?

18 MR. SNELL: Form.

19 THE WITNESS: It's always a combination  
20 of everything.

21 BY MR. SCHNIEDERS:

22 Q. But not including the mesh?

23 MR. SNELL: Same objection, form.

24 THE WITNESS: You can't have mesh



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1 erosion if mesh isn't part of the procedure, so  
2 in that context, mesh erosion necessitates  
3 previous placement of mesh.

4 BY MR. SCHNIEDERS:

5 Q. And in that context, does the mesh cause  
6 the erosion?

7 MR. SNELL: Form, incomplete  
8 hypothetical.

9 THE WITNESS: I think the opinion that I  
10 state in my report that the material itself  
11 does not cause the complication.

12 BY MR. SCHNIEDERS:

13 Q. Is there any mesh that causes that sort  
14 of complication that's on the market or has been taken  
15 off the market in the last ten years?

16 MR. SNELL: Form, vague.

17 THE WITNESS: I think my opinion is  
18 limited to, you know, the products being --  
19 what I prepared for and what I've written is  
20 specific to Prolift and Gynemesh PS. I'm happy  
21 to answer those questions as they relate to  
22 that.

23 BY MR. SCHNIEDERS:

24 Q. When you report an adverse event to the

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1 FDA, you're able to give an opinion as to whether or  
2 not the product that you're reporting the adverse event  
3 on was the cause or was related, correct?

4 A. Correct.

5 Q. Okay. Every time you reported an  
6 Ethicon product to the FDA as an adverse event, you  
7 said it wasn't related, correct?

8 MR. SNELL: Objection, lacks foundation.

9 THE WITNESS: I don't recall ever saying  
10 that I was concerned that the material itself  
11 was the problem.

12 BY MR. SCHNIEDERS:

13 Q. What about when you reported an Apogee?

14 A. Again, it could be patient selection, it  
15 could be patient risk factors, we usually report all  
16 those. You know, this was a smoker, obese patient who  
17 had previous surgery, you know. I mean, obviously, I  
18 don't identify the surgeon individually, but I will  
19 make comment whether they came locally, you know, from  
20 a local institution, whether they came from another  
21 state.

22 Again, my role is not to pass any kind of  
23 judgment or make any kind of decision. I'm simply  
24 reporting what I'm finding, and I trust it to the FDA

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1     that they're collecting similar information, if it does  
2     exist. So I'm simply reporting it in a non-judgmental  
3     manner. I'm not offering an opinion to them as far as  
4     what I think happened.

5             Q.       Well, there's a subsection of the form  
6     that allows for you to say it's related or not related,  
7     correct?

8             MR. SNELL: Foundation.

9             THE WITNESS: I don't recall  
10            specifically. It's been a number of years  
11            since I've had to report something. I wouldn't  
12            argue with you if you told me specifically that  
13            there was an area that said it was related.

14    BY MR. SCHNIEDERS:

15            Q.       It's been several years since you've  
16     reported anything as an adverse event?

17            A.       Two years, I would say. I can't give  
18     you an independent recollection of the last time that I  
19     reported something of that matter.

20            Q.       When was your last mesh revision  
21     surgery?

22            A.       Maybe six months ago.

23            Q.       You didn't report that as an adverse  
24     event?

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1           A.       So my understanding is that the FDA  
2       wants us to report on established products that were,  
3       you know, approved for the indication. So if somebody  
4       took a piece of Surgimesh or some Gortex mesh and had  
5       used it vaginally in the repair, and there was erosion  
6       of Gortex, which I think might have been the last one  
7       that I saw, I would not have reported that to the FDA.

8           But if someone had a manufactured product, like  
9       even things like NovaSure ablation or a device, you  
10      know, Therma -- whatever the Thermachoice device is or  
11      in this case Apogee Perigee, I report those type of  
12      cases.

13          Q.       When is the last time you did a revision  
14      on a product like that?

15          A.       Within the last year. I couldn't be  
16      more specific than that. There are not very common  
17      occurrences, fortunately, in our area.

18                   (Document marked for identification as  
19      Toggia Deposition Exhibit No. 4.)

20      BY MR. SCHNIEDERS:

21          Q.       So housekeeping wise, I think I marked  
22      as Exhibit 4 your box of your materials, and, as we  
23      said off the record, we're going to -- after the  
24      depositions tomorrow, you're going to put all your

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1 materials in that box and leave that with the court  
2 reporter; is that fair, Doctor?

3 A. We will have copies -- I just want to  
4 make sure that I have copies for further.

5 MR. SNELL: He is talking about after  
6 the depositions.

7 MR. SCHNIEDERS: After tomorrow.

8 MR. SNELL: Yeah, that's fine. Just  
9 make sure it gets back to Dr. Toggia. In TVT  
10 last time he had an issue where --

11 THE WITNESS: I didn't get the material  
12 for four months. So, unfortunately, counselor,  
13 prior experience has got my guard up, and I  
14 mean no offense to you.

15 MR. SCHNIEDERS: That's fair, and, of  
16 course, you know that has nothing to do with us  
17 either.

18 THE WITNESS: I'm willing, but if I seem  
19 hesitant or reluctant, once bitten, twice shy,  
20 but I plan to be fully cooperative with  
21 whatever the Court requests of me.

22 BY MR. SCHNIEDERS:

23 Q. And then Exhibit 5 I've actually  
24 separately marked, this will not go in that box.

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1 (Document marked for identification as  
2 Toggia Deposition Exhibit No. 5.)

3 BY MR. SCHNIEDERS:

4 Q. Exhibit 5 is your two invoices that you  
5 brought here today as well, okay?

6 A. Sure, yes.

7 (Document marked for identification as  
8 Toggia Deposition Exhibit No. 6.)

9 BY MR. SCHNIEDERS:

10 Q. Moving on to Exhibit 6, although I  
11 believe you have a copy of it over there, Doctor, your  
12 expert report.

13 A. Yes.

14 Q. Doctor, you are here today talking about  
15 your general expert report regarding Gynemesh PS and  
16 Prolift, correct?

17 A. That is correct.

18 Q. And this report, as we established  
19 earlier, was issued --

20 A. February 26, 2016.

21 Q. And that's your signature that appears  
22 on Page 25?

23 A. That is my signature.

24 Q. Does this report contain all of your

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1 opinions you intend to offer in this matter?

2 A. It does.

3 Q. And, obviously, we've been doing it up  
4 to this point, but if you need that to refer or to  
5 answer any questions, clearly, go to it and use it.

6 A. I appreciate that.

7 Q. I have copies here, just to be -- make  
8 sure I've got everything, but I have copies here of the  
9 TVT expert report that was marked as part of the  
10 previous deposition.

11 I assume nothing about your opinions has  
12 changed since the time of your deposition?

13 A. That's correct. Nothing has changed.

14 Q. I will not mark that.

15 So I also have reliance list, which I think we  
16 established earlier in the deposition is actually the  
17 reliance list for your TVT report, and my confusion  
18 came from the fact that it has the same date at the  
19 very top there, and it didn't say TVT, so I think we  
20 have a copy of your reliance list for the Gynemesh and  
21 Prolift report somewhere around here, don't we?

22 A. Right. It's not in the exhibit that you  
23 marked.

24 MR. SNELL: You can give that to him and

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1 mark that.

2 THE WITNESS: It's been in my report. I  
3 don't know what was provided to you, but my  
4 report is accurate.

5 MR. SNELL: You can give him that. That  
6 way he can mark it.

7 MR. SCHNIEDERS: I'm just going to mark  
8 that reliance list.

9 MR. SNELL: Sure.

10 MR. SCHNIEDERS: I'm marking Exhibit 7  
11 as that reliance list.

12 (Document marked for identification as  
13 Toggia Deposition Exhibit No. 7.)

14 BY MR. SCHNIEDERS:

15 Q. Doctor, what we've now marked as Exhibit  
16 7, I think we established earlier all the materials you  
17 brought today with you are somewhere on that list with  
18 the exception of one deposition that you've received I  
19 think since the TVT -- or I'm sorry -- since the actual  
20 report was issued; is that correct?

21 A. Yes, correct.

22 Q. And as we sit here today, you don't have  
23 any other materials to add to it or that you believe  
24 are missing, correct?



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1           A.       That is correct.

2                   MR. SNELL:   If I can say something, I  
3           just don't want there to be a misstatement on  
4           the record, and maybe I'm misremembering. I  
5           thought you had materials that Ostergard cited  
6           in his report too, or did you not have those?

7                   THE WITNESS: I showed this to you  
8           earlier, counselor. This is the -- these are  
9           the materials that Dr. Ostergard cited in his  
10          report that I don't believe were previously  
11          marked. Earlier you asked me about the  
12          educational materials that I did not have them  
13          in my personal records, but I did know that  
14          they were somewhere here.

15       BY MR. SCHNIEDERS:

16                Q.       And that binder is part of what I'm  
17       considering to be Exhibit 4 that's going to go in the  
18       box afterwards, fair?

19               A.       That's fair.

20                   MR. SNELL:   That makes sense.

21       BY MR. SCHNIEDERS:

22               Q.       And both the deposition and the  
23       materials from the Ostergard deposition and expert  
24       report are not a part of your reliance list, as it sits

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1 today, but you have reviewed them?

2 A. Because they came after the fact.

3 Q. Okay. But aside from the materials from  
4 the Ostergard expert report and that deposition,  
5 everything is on the reliance list?

6 A. That's correct.

7 Q. Doctor, who drafted the reliance list  
8 for you?

9 A. The list itself was drafted by  
10 Mr. Snell's office with the understanding that much of  
11 the material were studies and reports that I provided  
12 to them.

13 Q. Were there any materials that they  
14 provided to you that you did not ask for?

15 A. My recollection is that there were  
16 studies that I was familiar with that I may not have  
17 had a hard copy of, and I received a hard copy from  
18 them, but, in general, you know, you're looking at how  
19 I spend many of my nights and weekends over the past 25  
20 years, the type of materials that I read. So much of  
21 this is stuff that I've been familiar with for decades  
22 or from whenever it was published.

23 Q. So as I'm looking at your invoices, the  
24 last one was billed on February 29th of 2016, which was

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1 right about the same time, if not the same day --

2 A. Correct.

3 Q. -- that you issued your report.

4 So does that invoice encompass all the time  
5 that you spent up to the time you issued your report?

6 A. With regard to the general Prolift,  
7 Gynemesh report and the case specific reports, yes,  
8 separate from the TVT.

9 Q. Okay. So are these invoices that I'm  
10 looking at that we've marked as Exhibit 5, do they not  
11 include your work on TVT?

12 A. That's correct.

13 Q. Okay. There are separate invoices for  
14 that?

15 A. That's correct.

16 Q. And so you're keeping track of your  
17 time, whether you believe you're working on the Prolift  
18 side of things or the TVT side of things?

19 A. Separately, correct.

20 Q. I think that here as of January 31st of  
21 this year, you had 12 hours billed at \$400 an hour, and  
22 that was to the Ethicon Gynecare mesh litigation MDL,  
23 and it says 200, although, obviously, that's not the  
24 right MDL.

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1 Does that look correct.

2 A. Is it 2000? What's the --

3 Q. Well, either way, but that's as of

4 January 31st, that's the date that --

5 A. Yes. The inclusive dates are on the  
6 list and you can see -- I mean, I know you weren't at  
7 the TVT deposition, but we switched -- I switched gears  
8 after that, correct. So I believe it's a total of  
9 about 47 hours that was billed by the end of February,  
10 if I'm not mistaken.

11 Q. It's 35 on this one and then it was 12  
12 on this one, so 47 hours as of the time that you issued  
13 your report that you had spent working specific to  
14 these two products we're here today for?

15 A. Mm-hmm.

16 Q. Is that a yes?

17 A. Excuse me, that I've billed for.

18 Q. That you've billed for?

19 A. Correct.

20 Q. Okay. As we sit here, do you still have  
21 uninvoiced time?

22 A. I do.

23 Q. How much time would you estimate that  
24 you have that has not been billed?

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1           A.       I want to say maybe an additional 20  
2   hours.

3           Q.       And that goes to what my question was,  
4   and maybe I wasn't very clear, so I apologize. You  
5   issued your second invoice as of February 29th of 2016.

6                 Did that include -- because it says  
7   consultation fee, 2/1/16 through 2/29/16, did that  
8   include all the work that you had put in up until you  
9   signed your expert report?

10          A.       The question that you had asked me  
11   previously is what I billed them, and I've given you  
12   the information that I billed them. That would include  
13   all the work that I did up until the final date on that  
14   bill. Anything outstanding is subsequent to that date.  
15   Is that what you're asking.

16          Q.       Yeah. So this February 29, 2016 --

17          A.       There's no additional unbilled time for  
18   that time.

19          Q.       Okay. I apologize for being scattered  
20   on it. To make it clear --

21          A.       No, you were quite clear. You asked me  
22   what time I had billed and I answered what time I had  
23   billed. So I was clear on what you asked me,  
24   counselor.

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1 Q. So then as of March, so from the date  
2 that you signed your expert report forward, you've done  
3 an additional 20 hours approximately?

4 A. Approximately.

5 Q. Did that include deposition preparation  
6 time with Mr. Snell?

7 A. It will.

8 Q. Did you prepare for today's deposition?

9 A. Yes.

10 Q. How long did you spend with Mr. Snell or  
11 any of his partners to prepare?

12 A. Ninety minutes.

13 Q. So then the other 18 and a half hours or  
14 so would have been spent reading literature?

15 A. No. Again, not wanting to waste the  
16 Court's time, I wanted to read through the report and  
17 make some tabular notes, so when you asked me a  
18 specific question, I'd be able to find that information  
19 quickly, so reading, rereading, rechecking, summary  
20 type statistics. As I was provided, for example,  
21 Dr. Ostergard's deposition and materials, reviewing.

22 Q. I think you testified to this, but just  
23 so we're clear, when you met with Mr. Snell and anyone  
24 else from his office to prepare, they didn't show you

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1 any documents?

2 A. I'm not clear.

3 Q. Did they show you any documents when you  
4 were preparing for your deposition?

5 A. They provided me with Ostergard's.

6 Q. But that's it?

7 A. That's the example, yes.

8 Q. Anything else?

9 A. Specifically, no, not that I can think  
10 of.

11 Q. Have you ever seen any internal Ethicon  
12 documents?

13 A. I have seen Ethicon documents. I  
14 believe that was covered in the last TVT report. I do  
15 not think I've seen anything additionally since.

16 Q. The last TVT deposition?

17 A. Excuse me, the TVT deposition, correct.

18 Q. So has the defendant ever shown you any  
19 internal documents?

20 A. The ones that I just mentioned. There  
21 were documents provided -- there were documents of  
22 internal communication provided to me by Mr. Snell  
23 initially that were reviewed relevant to the TVT  
24 report. I mean, obviously, some of the information is

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1 relevant to the content today, but I've received no  
2 additional documents other than the ones that we listed  
3 for that report, and I believe they're listed on our  
4 reference list here as well.

5 Q. Anything that you're talking about that  
6 you had seen, you would have -- you believed it was on  
7 your reliance list for the TVT report?

8 A. I do believe, yes.

9 Q. Doctor, earlier you mentioned a product  
10 called the Sphinx.

11 Do you recall that?

12 A. I do.

13 Q. What was the Sphinx? Is it Sphinx or  
14 the Sphinx?

15 A. I think the project was just generically  
16 called Sphinx, as a pun on the word sphincter, and I  
17 believe we covered that during the TVT deposition.

18 Q. What is the Sphinx?

19 A. The Sphinx is a large stone structure in  
20 Cairo, Egypt. Sphinx was a project that looked at --  
21 Sphinx was a project that looked at whether or not we  
22 could extrapolate the integral theory to the posterior  
23 compartments specifically for fecal continence. It's  
24 my belief, as it is the belief of others, that the body



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1 doesn't go out of its way to come up with new  
2 mechanisms to control a common function. So if the  
3 body already has a functioning mechanism for the  
4 control of urinary -- of urine, that's similar type  
5 physiologic mechanisms might exist for fecal control.  
6 So we were exploring the feasibility of that, and that  
7 has also been explored by other surgeons with other  
8 companies.

9 Q. Doctor, would you say that, in your  
10 experience, Prolift and TVT have clearly shown that  
11 erosion occurs at the incision line all the time?

12 MR. SNELL: Form.

13 THE WITNESS: Can you repeat the  
14 question.

15 BY MR. SCHNIEDERS:

16 Q. Sure. Would you say that, in your  
17 experience, that Prolift and TVT clearly show that  
18 erosion occurs at the incision line all of the time?

19 MR. SNELL: Objection.

20 THE WITNESS: As a general rule, the  
21 exposure that I have seen and that I have read  
22 about tend to be in the incision line. Less  
23 commonly, you might see an erosion at other  
24 points of tension. Obviously, there are

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1           probably situations where the vaginal  
2           epithelium was unintentionally breached, and so  
3           then you would have exposure of mesh that was  
4           subsequently discovered that likely was there  
5           initially.

6       BY MR. SCHNIEDERS:

7           Q.       If there's more surface area of a sling  
8           that is directly below an incision, is there a higher  
9           risk of erosion?

10          A.       More surface area than what?

11          Q.       Than less surface area.

12                   MR. SNELL:   Form.

13                   THE WITNESS:  I'm not sure that I  
14           understand what you're asking me.

15       BY MR. SCHNIEDERS:

16          Q.       Is it better to eliminate as much  
17           surface area of sling directly below an incision in  
18           order to keep a lower rate of erosion?

19          A.       I don't believe so.

20          Q.       Does a larger surface area of sling  
21           directly below an incision increase the risk of  
22           erosion?

23          A.       Not that I'm aware of.

24                   (Document marked for identification as

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1                   Toglia Deposition Exhibit No. 8.)

2       BY MR. SCHNIEDERS:

3                   Q.       Let me show you what I've marked as  
4       Exhibit 8. This is an e-mail string from inside of  
5       Ethicon. At the very top you see that there's an  
6       e-mail from a gentleman named Gene Kammerer?

7                   A.       I do.

8                   Q.       Do you know Gene Kammerer?

9                   A.       I do.

10                  Q.       Who is Gene Kammerer?

11                  A.       Gene Kammerer I believe was an engineer  
12       consultant that worked with the R&D team at Ethicon on  
13       some of their projects. He's one of the project people  
14       that I worked with directly, probably was my most  
15       direct contact regarding the Sphinx or PASS procedure  
16       as we were considering it.

17                  Q.       And you see the subject he's responding  
18       to there says re: Dr. Toglia's comments on Sphinx and  
19       PASS.

20                  Do you see that?

21                  A.       Yes.

22                  Q.       Okay. And we don't need to go through  
23       that e-mail. You're welcome to look at it, if you  
24       like, but the very first e-mail is at the very bottom,

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1 and that's also from Mr. Kammerer, and on the second  
2 page it continues, "As you know I have been keeping a  
3 dialogue going with some of the advisory panel surgeons  
4 regarding our work and the concepts. Dr. Toggia has  
5 responded to the changes we made to the PASS concept  
6 and feels adamant that the 2 lateral incisions are  
7 crucial to its success. He has also provided some  
8 insight to the customer database which I haven't heard  
9 in our market research interviews. Here are some of  
10 his comments," and then you see what at least  
11 Mr. Kammerer is saying is a comment from you.

12 Do you see that?

13 A. Yes.

14 Q. Okay. Why don't you read that first  
15 paragraph right there regarding the two?

16 A. Regarding the 2 incisions versus a  
17 midline incision, as you know, there are many reasons  
18 why I feel that a single midline incision is a bad  
19 idea. Mostly, I am concerned about the erosion of the  
20 sling material through the perianal skin. Our  
21 experience with Prolift and TVT clearly show that  
22 erosions occur at the incision line all of the time,  
23 which is I think what I just stated to you. The  
24 perianal skin is very thin, and the sphincter is

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1 located very close to the skin. Therefore, a post anal  
2 sling will sit very close to the surface epithelium as  
3 well, and a crescent incision will significantly  
4 increase the surface area of sling directly beneath the  
5 incision and, therefore, the risk for erosion. A  
6 significant erosion rate will be the death of this  
7 procedure.

8 Q. This procedure, as we stated earlier,  
9 never made it to market; it was abandoned before it got  
10 there, correct?

11 A. I would like to think that it was placed  
12 on a shelf. Abandoned is kind of a cruel word for the  
13 parent of the concept.

14 Q. Well, at any rate, it's not on the  
15 market currently?

16 A. No. There are no sling based repairs on  
17 the market for this problem.

18 Q. Okay. And were you being truthful when  
19 you told Mr. Kammerer that the surface area of sling  
20 that is directly beneath the incision would increase  
21 the rate of erosion?

22 MR. SNELL: Objection, lacks foundation,  
23 assumes --

24 THE WITNESS: I mean, this was my

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1           theory, and I'm sorry, I mean, what you asked  
2           me earlier was -- I didn't hear you say below  
3           the incision. I simply heard you say below the  
4           epithelium. My point was at least in this  
5           location, you know, this is not the same  
6           location, by any means, compared to, say, the  
7           suburethral or the vagina but in basically the  
8           post anal area, it was at least my theory that  
9           we would be better off with separate lateral  
10          incisions as opposed to a contiguous incision.

11       BY MR. SCHNIEDERS:

12           Q.       Would you agree with this statement that  
13           a significant erosion rate would be the death of the  
14           procedure?

15                   MR. SNELL: Form, lacks foundation.

16                   THE WITNESS: No. I think that with  
17           regard to this particular concept, which was  
18           the PASS procedure, that I was concerned that  
19           that would be a significant limitation.  
20           Obviously, I had no data because there was no  
21           data to support that, but I was -- I don't  
22           think you can extrapolate what I'm saying here  
23           to anything other than the concept of what we  
24           have here.

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1 BY MR. SCHNIEDERS:

2 Q. What kind of mesh was used in the  
3 Sphinx?

4 A. Well, to be determined. We tried a  
5 variety of materials. I can't tell you that we ever  
6 got to that, you know, to the specific platform.

7 Q. Isn't it true that you started off with  
8 the concept of the TVT mesh?

9 A. Well, we had to play around with  
10 something, and what was readily available to Ethicon  
11 and Ethicon engineers were the TVT material, and so we  
12 did utilize TVT passers and the TVT mesh to see if we  
13 could anatomically place that material within that  
14 space.

15 Q. And that's the mesh you were using when  
16 you were concerned here in 2009 regarding erosions,  
17 correct?

18 A. One had nothing to do with the other.  
19 It had to do more with the type of incision being made,  
20 which is different than the type of -- we don't make  
21 lateral incisions next to the urethra.

22 Q. So you wanted to make a different type  
23 of incision, correct?

24 A. Given that we were operating close to

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1 the rectum where stool comes out of, you know, if I  
2 had -- you know, my concept was how can I locate the  
3 incisions a little bit away, away from the actual anal  
4 verge so that it's not in direct contact with the  
5 passage of stool. Additionally, considering the normal  
6 surface tension when a person sits down that would be  
7 placed on the perianal area, that's much more  
8 susceptible to say midline tension, we were looking at  
9 incisions that were non-midline, but, again, I don't  
10 think that this -- I don't think that I'm necessarily  
11 commenting on my concerns relative to the other  
12 procedures, but I was trying to use terms that they  
13 were familiar with based upon their other products.

14 Q. Like erosion?

15 A. I'm sorry.

16 Q. Terms they were familiar with on their  
17 other products like erosion?

18 A. No. I'm sorry, as far as the location  
19 of the incision. They were used to -- all of their  
20 sling products were done through a midline, vertical  
21 incision, and I was suggesting in this concept that the  
22 incisions be at a right angle to that, obviously in a  
23 different location, and I was trying to position -- I  
24 was trying to position the incisions away from the anal



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1     verge. And rather than one contiguous incision, I was  
2     suggesting two smaller incisions.

3             Q.       Fair to say that you were attempting to  
4     decrease the surface area of sling that was directly  
5     beneath the incision, correct?

6             MR. SNELL:   Form.

7             THE WITNESS:  There were many different  
8     things that I was thinking about doing. And,  
9     again, that's a very different area, the  
10    concerns are somewhat different. The tension  
11    lines are different. We now have the added  
12    possibility of stool, you know, close to the  
13    incision. I was simply trying to move the  
14    incisions away from the anal verge, as I've  
15    already stated.

16    BY MR. SCHNIEDERS:

17             Q.       And that's because your experience with  
18    Prolift and TVT clearly shows that the erosion occurs  
19    at the incision site all the time?

20             A.       No. It was for the reasons that I just  
21    mentioned. In my head, I was thinking I want to get  
22    these incisions away from the anal verge, away from the  
23    path of stool. I think that there's different surface  
24    tension forces next to the anus, and so I at least

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1 wanted to start with the concept would it be feasible  
2 to place the incisions there.

3 And they would say, well, why, why do you think  
4 that? And I would, again, try to communicate to them  
5 in their own language, and I would say, well, as you  
6 know, we were aware of circumstances where the slings  
7 are showing exposure, and, you know, the one factor at  
8 the time that was being considered was the location or  
9 type of incision.

10 The French, when they did their TVM products,  
11 also were looking at transverse incisions as opposed to  
12 midline incisions.

13 Q. Doctor, yes, no or you can't answer,  
14 larger surface area of sling directly beneath an  
15 incision increases the risk of erosion?

16 MR. SNELL: Objection, asked and  
17 answered. You don't have to answer it yes, no  
18 or I don't know. You told him before.

19 THE WITNESS: I've already stated my  
20 answer, counselor. I'm really trying not to be  
21 difficult. I honestly -- and I realize that  
22 you have no expertise in this area of the body,  
23 but there were unique challenges working near  
24 the rectum, and I was trying to address those,

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1           you know, again, just based on theory. There's  
2           no evidence that what I said would have borne  
3           out to be true. It may have turned out that a  
4           midline incision was perfectly feasible and/or  
5           easier. I was just starting with a slightly  
6           different concept for the reasons that I  
7           explained.

8                     In addition, there was another product  
9           in development for a similar indication, and I  
10          was trying to make this one different, you  
11          know, in its approach.

12       BY MR. SCHNIEDERS:

13                 Q.       So the reason you said the Sphinx at  
14          that time was because you were trying to differentiate  
15          the product and because you had a theory that  
16          potentially the surface area of the sling above the  
17          incision site could increase the risk of erosion,  
18          correct?

19                     MR. SNELL:   Objection, misstates.

20                     THE WITNESS:   One of a number -- again,  
21          I was trying to explore a unique concept that  
22          whether or not this would work to our  
23          advantage. You know, obviously we already had  
24          experience with midline incisions. In general,

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1           they worked well. I was trying to come up with  
2           a more unique concept. You know, with two  
3           separate incisions, I was hoping that there  
4           would be no tension at the midpoint or directly  
5           beneath the incision line.

6       BY MR. SCHNIEDERS:

7           Q.       But you weren't concerned about the  
8           amount of surface area of the sling beneath the  
9           incision, correct?

10          A.       I would say yes. I would say surface  
11       area was really not my concern but, again --

12          Q.       That's what you wrote down here?

13          A.       I understand.

14                 MR. SNELL: Actually, no, you're  
15       misstating. That is not his writing, so don't  
16       say he wrote that.

17                 THE WITNESS: That's true, good point.

18                 MR. SNELL: That lacks foundation.

19       BY MR. SCHNIEDERS:

20          Q.       Are you saying that you didn't have a  
21       conversation about this topic with Gene Kammerer?

22          A.       No, no. I'm saying I had a  
23       conversation. I'm just saying I did not write these  
24       paragraphs, that these are not my words, okay. But,

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1 again, I was trying to explain to them in terms that an  
2 engineer, who is familiar with the different product,  
3 would understand. But, obviously, I did not edit --  
4 write or edit this information.

5 Q. Did you ever e-mail with Mr. Kammerer?

6 A. Yes.

7 Q. Are you able to testify this wasn't an  
8 e-mail that he had cut and pasted into this e-mail that  
9 he sent?

10 A. I have no idea, sir.

11 Q. And did you go to look in your own  
12 personal e-mails to see if you could find this one from  
13 2009?

14 A. I no longer own -- I no longer have --  
15 that computer has been destroyed along with all of its  
16 material. I don't own the rights to this concept, so I  
17 was informed to discard all of that once the product  
18 was abandoned, as you so put it.

19 Q. And you went through and cleaned out all  
20 of your e-mails and deleted all of them at that point?

21 A. I deleted all of those e-mails and then  
22 when I wiped the hard drive on that computer, that just  
23 went wherever those bits go, yes.

24 Q. Sure, sure. But there's a server

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1 somewhere where those e-mails probably exist; you know  
2 that?

3 A. I don't know. I don't know. I honestly  
4 don't know.

5 Q. What account would you have been using  
6 at that time to communicate with Mr. Kammerer?

7 A. I honestly don't know.

8 (Document marked for identification as  
9 Toggia Deposition Exhibit No. 9.)

10 BY MR. SCHNIEDERS:

11 Q. Let me mark as Exhibit 9 another e-mail  
12 from Mr. Kammerer.

13 Is it possible that this e-mail address that  
14 you sent him an e-mail from, that's a Verizon address,  
15 is that the one you might have been using?

16 A. It would seem to me that this would be  
17 the account that I e-mailed him from, correct.

18 Q. Do you currently have the Verizon.net  
19 e-mail address?

20 A. Yeah, and I would appreciate for privacy  
21 reasons if we didn't go into any more detail than that,  
22 given that this is a public document.

23 Q. I'm assuming he's going to ask to have  
24 most of this sealed, to be honest.

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1 MR. SNELL: We'll go ahead and seal  
2 anything personal.

3 THE WITNESS: I apologize, but there are  
4 concerns about identity theft and information  
5 that I have.

6 BY MR. SCHNIEDERS:

7 Q. I'm not going to e-mail you, I promise.

8 A. Yes. So, again, this represents sort of  
9 my emotional response perhaps, and, again, remember as  
10 the parent to the concept, I was a little bit resistant  
11 to people wanting to change my concept because I  
12 thought that I had thought them out pretty clearly.

13 Q. So, Dr. Toggia, if you go to the e-mail  
14 down below where you're actually e-mailing to  
15 Mr. Kammerer, and the subject is re: checking in,  
16 because I think if you go back there was originally an  
17 e-mail from you asking if the project was dormant?

18 A. Sure.

19 Q. But if you see here the third, and this  
20 is I think what you're talking about your emotional  
21 response to the way that they were approaching the  
22 project perhaps, but that third line starting  
23 "Ethicon," could you read that sentence or that  
24 paragraph there?

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1           A.       I'm happy to. Let me just make sure I  
2 understand you clearly. You want me to begin reading  
3 the paragraph entitled "another key concept."

4           Q.       No. The one that starts with "Ethicon  
5 has enjoyed."

6           A.       Oh. Ethicon has enjoyed its greatest  
7 success with simple, straightforward thin sling - the  
8 TVT. Attempts to develop more comprehensive mesh  
9 solutions have far -- have not only been far less  
10 successful, but as a class have had serious  
11 complications and are rapidly falling out of favor.

12          Q.       What mesh solutions, comprehensive mesh  
13 solutions were you talking about there?

14          A.       I honestly don't know. This is from six  
15 years ago. These may have been other concept projects  
16 that -- at one point I sat down with them and we went  
17 over eight to ten new concepts for other projects  
18 within this sphere. Obviously, I would think in my  
19 mind if it was an existing project, I would have used  
20 the existing product's name.

21          Q.       How many comprehensive mesh solutions  
22 can you think of that have had serious complications?

23          A.       As a class, I don't know of any actually  
24 at this point.



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1 Q. Well, then what did you mean?

2 A. I might have been referring specifically  
3 to the IVS Tunneller. You know, the IVS Tunneller,  
4 this was a concept that also involved the tunneling of  
5 mesh through several compartments over a long period of  
6 time, and the IVS Tunneller was also in its initial  
7 form both anterior and posteriorly involved similar  
8 type concepts. So now that I sort of reinvigorate my  
9 brain, I wouldn't be surprised if I'm referring to the  
10 IVS Tunneller in this statement.

11 Q. You're referring to the IVS Tunneller  
12 with regard to Ethicon because it says Ethicon products  
13 right there?

14 A. I didn't say that Ethicon's attempts, I  
15 just said attempts. The bottom line is that I don't  
16 recall, as I sit here, specifically what I was  
17 referring to in this e-mail. I'm sorry.

18 Q. So it could be that you're talking about  
19 things like Gynemesh PS, correct?

20 MR. SNELL: Objection, lacks foundation.

21 THE WITNESS: I highly doubt this had  
22 anything to do with the Gynemesh PS.

23 BY MR. SCHNIEDERS:

24 Q. Could have been Prolift, right?

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1 MR. SNELL: Same objection.

2 THE WITNESS: I honestly don't think it  
3 had to do with Prolift, in all honesty.

4 BY MR. SCHNIEDERS:

5 Q. Explain for the jury what the Tunneller  
6 does.

7 A. Explain to you?

8 Q. To the jury, you're talking to the jury  
9 right now.

10 A. Am I talking to the jury right now? Is  
11 that who I'm talking to?

12 MR. SNELL: You can just answer his  
13 questions to the best of your ability.  
14 Sometimes lawyers say things --

15 THE WITNESS: I'm sorry. Got you. I  
16 mean, I'm just very literal, and I just want to  
17 make sure I don't misstate anything. Well, I  
18 mean, obviously, to deliver a product to its  
19 destination and whether it's laparoscopy or  
20 cannulas for TVT, cannulas for Prolift, you  
21 have to have a way to deliver the product to  
22 its final destination, and, again, the PASS  
23 concept involved placing a mesh sling below the  
24 anal sphincter and towing it up, if I remember

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1           correctly, through the obturator space as a  
2           point of exit.

3       BY MR. SCHNIEDERS:

4           Q.       And what were the serious complications  
5           that were related to that?

6           A.       There weren't anything. The PASS  
7           concept never was done in a live person.

8           Q.       So, sitting here today, you can't think  
9           of any comprehensive mesh solutions that were developed  
10          as a class that have had serious complications and are  
11          rapidly falling out of favor that you might have been  
12          referencing in January of 2010?

13                 MR. SNELL: Objection, asked and  
14          answered.

15                 THE WITNESS: Yes, I mean, again, I  
16          cannot tell you what I specifically had in mind  
17          behind that statement. I was clearly, as you  
18          can see from the overall emotional tone of the  
19          letter, of the e-mail that I was being very  
20          emotionally resistant to the idea that we  
21          change anything. We hadn't even done anything  
22          with it yet. I wanted to test the original  
23          idea, as I had laid it forth to see what the  
24          feasibility was, and I was not open at the time

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1 to making changes.

2 BY MR. SCHNIEDERS:

3 Q. But sitting here today, you're sure that  
4 it's not Prolift that you were talking about?

5 A. I don't recall it as being Prolift at  
6 the time, no.

7 Q. And you're sure it's not Gynemesh PS  
8 that you're talking about?

9 A. You know, I think I would have listed it  
10 by name. I listed their success by name. I think if I  
11 had a specific concern, I would have listed that as  
12 well.

13 Q. You didn't mention Tunneller there, did  
14 you?

15 A. No. I was talking about just the  
16 overall where we were conceptually, you know, at the  
17 time.

18 MR. SCHNIEDERS: Maybe now is a good  
19 time to take a break.

20 (Brief recess taken at 3:27 p.m.)

21 (Deposition resumes at 3:38 p.m.)

22 MR. SCHNIEDERS: We're back after a  
23 short break.

24 MR. SNELL: Let's mark that last portion

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1 confidential. Let's mark the whole thing. For  
2 the purpose of whoever is going to be reviewing  
3 this on this issue, there are discussions about  
4 intellectual property concepts, thoughts by the  
5 doctor and what not which he has concerns about  
6 it falling into other people's hands. That is  
7 the basis and the purpose.

8 THE WITNESS: Thank you.

9 BY MR. SCHNIEDERS:

10 Q. Doctor, are you doing any current  
11 research on polypropylene meshes?

12 A. I mean, I consider the reviews that I do  
13 here where, you know, basically systematic review is a  
14 type of, you know, research project. In terms of --  
15 I'm not currently engaged in any clinical trials of  
16 that material.

17 Q. Are you engaged in any attempts to  
18 publish any retrospective data or anything like that?

19 A. My current role in that arena is that,  
20 you know, since I serve as an editor of two journals,  
21 my energy is spent actually reviewing studies and  
22 manuscripts submitted for publications, much of which  
23 is on the subject matter that we're discussing today,  
24 but I have no -- I have nothing pending to be

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1 published.

2 Q. Have you ever written anything on the  
3 Burch procedure?

4 MR. SNELL: Form.

5 THE WITNESS: There may be mention in a  
6 book chapter, but I have not published on my  
7 personal experience with that procedure  
8 independent from a more general discussion.

9 BY MR. SCHNIEDERS:

10 Q. Have you ever written anything on  
11 biologic tissue slings?

12 A. I have not.

13 Q. You would agree that you're not an  
14 academic physician, correct?

15 MR. SNELL: Form.

16 THE WITNESS: I would not agree with  
17 that, no.

18 BY MR. SCHNIEDERS:

19 Q. Explain, please.

20 A. Much of the work that I do is equivalent  
21 to what you do in academics. I was previously employed  
22 at an academic institution. I'm simply not employed by  
23 an academic institution. Obviously, I have  
24 appointments at an academic institution. Our current

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1 institution involves -- does have a residency, so I am  
2 directly involved in teaching and the creation of  
3 academic curriculum, resident education, resident  
4 teaching. I do speak nationally in postgraduate  
5 medical educations through venues such as AUGS, Society  
6 of Gynecologic Surgeons. Those are academic endeavors.

7 Q. But you also have a private clinical  
8 practice, correct?

9 A. Correct.

10 Q. So insofar as you are a private clinical  
11 physician, in that portion of your life, that would not  
12 be academic medicine, correct?

13 MR. SNELL: Objection.

14 THE WITNESS: I disagree. Again, before  
15 I came here today, I was in the operating room  
16 in my private practice. I had a resident with  
17 me and a medical student with me. That is  
18 academic in nature. We are discussing and  
19 teaching. So it's all of the above.

20 BY MR. SCHNIEDERS:

21 Q. I may have asked this before, so forgive  
22 me if I have. Are you currently under contract as a  
23 consultant for any pharmaceutical or device company?

24 A. You did not ask that before. I

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1 currently consult with a pharmaceutical company. I had  
2 a consulting -- an active consultant agreement with a  
3 medical device company that if we wait another week  
4 will no longer exist.

5 Q. So would that be AMS?

6 A. That would be, very good.

7 Q. And who is the pharmaceutical company  
8 you consult with currently?

9 A. So it would be Astellas Pharma whom I've  
10 consult with since 1994, I believe, unrelated to what  
11 we're discussing today.

12 Q. And would that be the longest standing  
13 relationship you have in consulting with a  
14 pharmaceutical or a device company?

15 A. I believe so.

16 Q. Have you continuously worked for  
17 Astellas since 1994?

18 A. I have never worked for Astellas.

19 Q. Point taken. Have you continuously  
20 worked with Astellas since 1994?

21 A. You know, intermittent relationship.  
22 There are periods of time, different cycles of the  
23 economy where they are more interested, less  
24 interested. It varies widely. I would say, as a



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1     general rule, my involvement in the past several years  
2     has been fairly minimal.

3             Q.       You would agree that less rigidity with  
4     regard to mesh is better, correct?

5             MR. SNELL:   Form, overbroad, lacks  
6     foundation.

7             THE WITNESS:   I would not agree.

8     BY MR. SCHNIEDERS:

9             Q.       Okay.   Explain to me why not.

10            A.       I'm not sure what the foundation is that  
11     you're asking me.   Less better for what?

12            Q.       Less likely to cause or impair -- strike  
13     that.

14            Less likely to impair sexual function?

15            MR. SNELL:   Same objection, incomplete  
16     hypothetical.

17            THE WITNESS:   Yeah, it's more  
18     complicated than that, counselor.   Please keep  
19     in mind that we don't have any cutoffs or  
20     agreements, there are no expert consensus as  
21     far as what's lightweight, what's not  
22     lightweight, what's rigid, what's less rigid,  
23     you know.   These are just sort of a continuum  
24     of ideas.   You know, everything is relative.

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1           You know, is this lightweight, well, it might  
2           be lighter than something previously, not as  
3           light as something later. But, in general, my  
4           objection is that we don't have cutoffs, no one  
5           has ever published, you know, this is heavy,  
6           this is light. There's no expert consensus.  
7           People do throw around the terms relatively,  
8           this is lighter weight mesh, this is  
9           lightweight, but I don't know what the cutoffs  
10          are, and the same would apply to rigidity.

11          Q.       So there are cutoffs, you just don't  
12          know what they are?

13                 MR. SNELL: Objection.

14                 THE WITNESS: If I don't know -- if I  
15                 don't know what they are, how would I know that  
16                 there were cutoffs?

17          BY MR. SCHNIEDERS:

18          Q.       You said but I don't know what the  
19                 cutoffs are, and the same would apply to rigidity.  
20                 That implies that there are cutoffs somewhere, right?

21                 MR. SNELL: I'm going to object.

22                 THE WITNESS: No.

23                 MR. SNELL: Hold on. You have to let me  
24                 object. You're actually misstating his

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1 testimony. His testimony he did say there is  
2 no cutoff.

3 MR. SCHNIEDERS: I'm again going to read  
4 because I don't need you to speak for the  
5 witness.

6 MR. SNELL: I'm not speaking, but you  
7 are misstating his testimony --

8 MR. SCHNIEDERS: I'm reading from it  
9 right here.

10 MR. SNELL: His answer was 21 lines  
11 long.

12 MR. SCHNIEDERS: He said I don't know  
13 what the cutoffs are and the same would apply  
14 to rigidity.

15 MR. SNELL: No, his answer was 20 lines  
16 longer than the little thing you pulled out of  
17 there.

18 MR. SCHNIEDERS: Whatever.

19 BY MR. SCHNIEDERS:

20 Q. Are there cutoffs?

21 A. There are currently no established  
22 cutoffs, there are no definitions, and there is no  
23 expert consensus.

24 Q. But, theoretically, there are cutoffs

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1       somewhere, right?

2                       MR. SNELL:   Form, hypothetical.

3                       THE WITNESS:   No.

4       BY MR. SCHNIEDERS:

5               Q.       No?

6               A.       There are no established, universally  
7       accepted definitions, cutoffs, consensus of opinion.

8               Q.       Doctor, listen to my question.   I said  
9       theoretically, there are cutoffs.   I didn't say they  
10      were established, universally accepted cutoffs.   I said  
11      theoretically there would be cutoffs, right?

12               MR. SNELL:   Objection, vague, calls for  
13      speculation.

14               THE WITNESS:   I don't know how further  
15      to answer that.   I'm sorry.

16      BY MR. SCHNIEDERS:

17               Q.       Why hasn't AUGS filed a consensus  
18      statement on what levels of rigidity are acceptable?

19               A.       I can't answer that question.   I can't  
20      speak for AUGS.

21               Q.       Are you a member of that society?

22               A.       Yes.

23               Q.       Have you ever gone to them and said why  
24      don't we put out a consensus statement on this?

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1 A. No, I have not.

2 Q. Did you go to them and have any input in  
3 their position statement regarding vaginal mesh?

4 A. I did not have any direct input into  
5 that statement.

6 Q. Did you ever review a draft of that  
7 statement?

8 A. I don't believe that I reviewed a draft  
9 of that statement.

10 Q. Were you ever circulated a draft of that  
11 statement?

12 A. I might have been circulated a draft of  
13 that statement. I don't independently recall that.

14 Q. And not to -- honestly not to make you  
15 uncomfortable, but had you received a draft of that  
16 statement, would that have been to that Verizon e-mail  
17 address?

18 MR. SNELL: Objection.

19 THE WITNESS: I don't know. I don't  
20 know. That would be one of the more common  
21 addresses that I might receive material, but I  
22 didn't receive it.

23 BY MR. SCHNIEDERS:

24 Q. You didn't receive it, or you don't know

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1 if you received it?

2 A. I think it's the same thing. I do not  
3 recall that I have ever received a draft, to the best  
4 of my knowledge, of that statement, of the proposed  
5 statement.

6 Q. Sorry didn't mean to interrupt.

7 Do you know who the authors are of that  
8 statement?

9 A. I do.

10 Q. Do you know them personally?

11 A. I do.

12 Q. Do you consider yourself to be friends  
13 with those gentlemen?

14 A. They are colleagues of mine.

15 Q. Are they people you would see socially  
16 as well or just professionally?

17 A. I think those lines are blurred in my  
18 area, as I'm sure they are in yours. You know, we have  
19 social events at our academic meetings, our scientific  
20 meetings. I don't believe I was in any of their  
21 wedding parties or went on vacation or sat in a Jacuzzi  
22 with any of them, but I would say, certainly, you know,  
23 I think it would be accurate to say that we have  
24 collegial relationships that are both social and

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1 academic.

2 Q. Have you ever discussed authoring  
3 anything with any of them?

4 A. I would have to look at the  
5 comprehensive list of the people on that if you want to  
6 share that with me.

7 Q. We can cover that in a moment.

8 A. Yeah.

9 Q. You are not an expert in chemical  
10 engineering, correct?

11 MR. SNELL: Form. This is covered in  
12 the earlier deposition.

13 MR. SCHNIEDERS: And I am aware and  
14 that's why I'm asking it.

15 BY MR. SCHNIEDERS:

16 Q. Do you hold yourself out as an expert in  
17 chemical engineering?

18 A. I think -- no, I don't hold myself out  
19 in a general sense in chemical engineering. I think I  
20 have expertise in this particular arena in front of any  
21 audience that I might be asked to participate as it  
22 relates to polypropylene mesh being used for its  
23 intended purpose.

24 Q. You're not an expert in pathology,

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1 correct?

2 MR. SNELL: Objection.

3 THE WITNESS: I'm -- I don't have any  
4 certification in pathology. I have certainly  
5 an in-depth knowledge and, again, you know, if  
6 we were to go to the Villanova game together,  
7 I'd probably know more than the majority of  
8 people at that game.

9 BY MR. SCHNIEDERS:

10 Q. But you would defer to a pathologist,  
11 correct?

12 A. I don't know what you mean by "defer."  
13 I mean, if we had a disagreement, I wouldn't stand up  
14 and say you're a pathologist, you're absolutely right.  
15 No, I wouldn't defer in that regard.

16 Q. So you believe that you have an equal  
17 expertise as a pathologist?

18 A. I don't know where you're getting this  
19 from. I never made that statement.

20 Q. You would agree that a pathologist has a  
21 greater expertise in pathology than you do?

22 MR. SNELL: Form.

23 THE WITNESS: Yes, I would say, in a  
24 general sense, a pathologist has a more



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1 in-depth level of knowledge than I.

2 BY MR. SCHNIEDERS:

3 Q. You agree you're not an expert in  
4 polymer chemistry, correct?

5 MR. SNELL: Objection, asked and  
6 answered in earlier deposition.

7 THE WITNESS: I think relative to the  
8 topic at hand, I would be considered by many to  
9 possess expertise in polymer chemistry.

10 BY MR. SCHNIEDERS:

11 Q. Relative to a jury, but not relative to  
12 a polymer chemist, correct?

13 MR. SNELL: Same objections.

14 THE WITNESS: You know, in terms of the  
15 application of this material within the human  
16 body, I've got a pretty good understanding of  
17 the working of polymer, yes. I have a degree  
18 in biochemistry. I've been reviewing this  
19 material extensively. I am certainly reading  
20 materials that are beyond what the average  
21 gynecologist or even urogynecologist female  
22 pelvic medicine or urologist would have  
23 reviewed.

24 BY MR. SCHNIEDERS:

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1 Q. When was that degree in biochemistry?

2 A. 1985.

3 Q. And when is the last class you took in  
4 biochemistry?

5 A. Well, I mean, I'm constantly reading  
6 material. Obviously at this stage of the game I don't  
7 pay to enroll in college courses, but my -- you know,  
8 foundation of my knowledge did not end when I graduated  
9 from college.

10 Q. When is the last class you took in  
11 biochemistry?

12 A. I took a class in medical school in  
13 biochemistry.

14 Q. About what year would that have been?

15 A. That would have been 1986, '87.

16 Q. You've never done bench research on  
17 polypropylene, correct?

18 A. I have not.

19 Q. You've never done lab research on  
20 polypropylene, correct?

21 A. I have not.

22 Q. You've never done any sort of  
23 pathological analysis on explanted polypropylene, have  
24 you?

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1 MR. SNELL: Form.

2 THE WITNESS: I have not. Understand  
3 that I've done lab work as it pertains to my  
4 consultation with polypropylene products in  
5 medical, you know -- in the medical arena.

6 BY MR. SCHNIEDERS:

7 Q. When you explant mesh, what do you do  
8 with that mesh?

9 A. The majority, depending upon -- you  
10 know, depending upon the situation, the majority of  
11 that material is sent to pathology for identification  
12 and labeling.

13 Q. Okay. You don't do that yourself, you  
14 send it to a pathologist?

15 A. Well, I'm operating on a patient, so I  
16 can't do both things, so I will send that to the  
17 pathologist.

18 Q. Could you?

19 A. Could I what?

20 Q. Could you do what the pathologist does?

21 A. Given that what the pathologist does is  
22 typically measure the dimensions of the material and  
23 simply reports that I have in front of me a 2 by 1  
24 centimeter piece of blue mesh, that I can do, correct.

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1 I can't tell you that in the medical world that there's  
2 any further analysis being done routinely.

3 Q. You've never published any opinion that  
4 polypropylene does not cause a foreign body reaction,  
5 correct?

6 A. Well, that's a double negative so -- and  
7 I do want to answer you accurately, so if you can  
8 restate that question without a double negative, I  
9 would appreciate it.

10 Q. Have you ever published an opinion that  
11 polypropylene does not cause a foreign body reaction?

12 A. Of course, polypropylene causes a  
13 foreign body reaction. Any foreign material implanted  
14 in the body will cause a foreign body reaction. That's  
15 what foreign body reaction is by definition.

16 Q. You are not an expert on warnings,  
17 correct?

18 MR. SNELL: Objection.

19 THE WITNESS: I don't hold myself out to  
20 offer an expert opinion on warnings, although I  
21 have, you know, ample experience in, you know,  
22 reading about them and reading those materials.

23 BY MR. SCHNIEDERS:

24 Q. You're not a biomechanical engineer,

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1 correct?

2 A. I am not, no.

3 Q. I think we're going to get sideways  
4 here. You are not an expert on the design of medical  
5 devices, correct?

6 MR. SNELL: Objection, covered in his  
7 first deposition extensively.

8 THE WITNESS: I have worked on the  
9 design of medical devices. I have worked on  
10 the design and redesign of existing devices, as  
11 well as the device -- the medical device that  
12 we referred to earlier as the PASS device.

13 BY MR. SCHNIEDERS:

14 Q. And have you ever designed a device that  
15 made it to market?

16 A. I have not.

17 Q. I don't say that to cruel.

18 A. No, I apologize. I had -- and, again,  
19 I'm a relatively humble person. I had extensive input  
20 into the design of the TVT Exact, which is currently on  
21 the market.

22 Q. You had extensive input into the design  
23 before it went to market?

24 A. Correct.

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1 Q. Do you know what standards a  
2 manufacturer must follow in designing mesh products?

3 A. I have a general awareness, a general  
4 awareness only.

5 Q. But you couldn't cite us CFRs or  
6 statutes or anything like that, correct?

7 A. I couldn't cite it, no.

8 Q. Have you ever seen the statutes that  
9 relate to the responsibilities a manufacturer holds in  
10 designing a product?

11 A. I don't recall, no.

12 Q. Have you ever reviewed any of Ethicon's  
13 standard operating procedures relating to design?

14 A. I do not believe so.

15 Q. Do you know what a clinical expert  
16 report is?

17 A. I believe this is the second one that  
18 I've issued in this arena, if I'm not mistaken. Is  
19 this what we're referring to?

20 Q. What you've issued is a clinical expert  
21 report, that's your definition of it?

22 A. Yes.

23 Q. Do you know what a design history file  
24 is?

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1 A. In a general sense.

2 Q. What is it?

3 A. You know, when a manufacturer sets out  
4 to design a product, they would keep track of the  
5 history of that development and they would keep track  
6 of the communications between the different parties and  
7 the steps along that -- along that design.

8 Q. All right, Doctor. So earlier we were  
9 talking about two days that you put in the Gynemesh PS  
10 on your operating days.

11 What days are your operating days currently?

12 A. How is this relevant to the testimony  
13 that I'm giving? I operate two days a week. Is that  
14 not sufficient information?

15 Q. If you really don't want me to know what  
16 day, it's fine.

17 A. Yes, thank you.

18 Q. Two days a week?

19 A. Correct.

20 Q. And that's every week?

21 A. Correct.

22 Q. And how many surgeries do you do on  
23 those two days, typically?

24 A. Sure, I previously answered that on

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1 average, I'll do between six and eight procedures, and  
2 they are virtually all related to pelvic floor  
3 disorders.

4 Q. Are there any surgeries that you're  
5 doing currently that are not related to pelvic floor  
6 disorders?

7 A. There may be some surgeries that are  
8 more general gynecology in nature. For example, if a  
9 woman is sent to me with prolapse and she tells me she  
10 has bleeding, I may first have to do a D&C or a biopsy  
11 or some other general thing prior to completing the  
12 treatment for the prolapse. So I would say it's within  
13 the sphere of gynecologic surgery and urogynecologic  
14 surgery.

15 Q. So vast majority of your procedures  
16 currently are going to be a TVT product or the Gynemesh  
17 PS, correct?

18 A. No. The vast majority of my procedures  
19 are prolapse and incontinence. Procedures, the  
20 prolapse procedures could be native tissue plication,  
21 obliterative procedures, Gynemesh or sacrocolpopexy  
22 procedures. The majority of my incontinence procedures  
23 are retropubic TVT procedures, specifically TVT Exact.

24 Q. So out of approximately 12 surgeries



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1     that you perform weekly, how many of those surgeries  
2     are likely to be Gynemesh PS?

3             A.       I didn't say I did 12 surgeries a week,  
4     for clarification. I said I did between six and eight  
5     procedures a week.

6             Q.       Oh, I thought that was per day.

7             A.       No, I'm sorry.

8             Q.       Okay. Six to eight per week?

9             A.       Correct.

10            Q.       So spread out over the two days?

11            A.       Correct, right.

12            Q.       And of those six to eight, how many are  
13    Gynemesh PS, typically?

14            A.       I would say it may range from two to  
15    four.

16            Q.       And with the understanding that,  
17    typically, it's going to be TVT Exact, how many are  
18    TVT?

19            A.       Again, I would say as an average range  
20    two to four, it could be five. It could be four to  
21    five in a single day.

22            Q.       So these are procedures that on a weekly  
23    basis you are discussing with patients and then  
24    performing, correct?

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1           A.       I would say on a daily basis, whether  
2   it's in the office or in the operating room, I am in  
3   constant, you know, dialogue, examinations that would  
4   involve these type of products, absolutely.

5           Q.       So specific, and, you know, I guess we  
6   haven't said this, but is the Prolift on the market  
7   right now?

8           A.       It is not.

9           Q.       Why is that?

10          A.       The manufacturer decided to withdraw the  
11   product from the market.

12          Q.       Was there FDA action that preceded that?

13          A.       It's my understanding that the FDA  
14   wanted to require very specific research at certain  
15   endpoints. Moving forward the company felt that they  
16   had already invested a significant amount of resources  
17   and felt that they had already adequately demonstrated  
18   what the FDA was asking for, but the FDA was not  
19   satisfied with what had been provided and wanted  
20   everything to sort of be redone.

21          Q.       And, to your understanding, what did  
22   Ethicon do in response to that?

23          A.       Again, I wasn't involved at that level  
24   in the decision-making itself. It's my understanding

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1     that they chose to withdraw the products, the family of  
2     products on the market.

3             Q.       Rather than perform the studies that the  
4     FDA was asking for?

5             A.       I mean, I don't know that it's a rather  
6     than. They just decided to withdraw the products.

7             Q.       And the defendants haven't made you  
8     privy to any of the internal communications regarding  
9     this business decision, have they?

10            MR. SNELL: Who? Answer to your  
11            recollection.

12            THE WITNESS: To my recollection, I  
13            don't remember being privy to that information,  
14            no.

15            MR. SCHNIEDERS: Do you have a --

16            MR. SNELL: Well, I mean, he has the 522  
17            orders and the back and forth of what the FDA  
18            said, if that's what you're talking about. I  
19            should have objected because your question was  
20            a little vague. I wasn't quite sure what you  
21            were talking about exactly.

22            MR. SCHNIEDERS: I said internal -- you  
23            got real time right there, just read it. It  
24            says and the defendants haven't made you privy

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1 to any of the internal communications regarding  
2 this business decision, have they, and I think  
3 the answer is no, to your recollection.

4 MR. SNELL: I don't know. I haven't  
5 looked through everything Ostergard has, and  
6 there's a huge binder, and if it's in his  
7 stuff, it's been given to him.

8 THE WITNESS: But, no, I have not.

9 BY MR. SCHNIEDERS:

10 Q. Okay.

11 A. In my recollection is that I have not.  
12 I don't recollect, rather. I'm sorry.

13 Q. And the most recent things that you  
14 might have read would have been Ostergard, correct?

15 A. I don't recall reading any of that in  
16 Ostergard, but, no.

17 Q. Have you asked the defendant for any of  
18 those internal communications?

19 A. I have not.

20 Q. Why not?

21 A. I don't consider them to be relevant to  
22 my generating the expert report.

23 Q. You're not curious what their  
24 decision-making process was in to why they wouldn't do

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1 extra testing?

2 MR. SNELL: Form, foundation.

3 THE WITNESS: I have no curiosity in  
4 that domain. I have plenty of other work to  
5 occupy my time.

6 BY MR. SCHNIEDERS:

7 Q. But, as we sit here today, and we've  
8 established from your expert report you believe that,  
9 for instance, the Prolift is a safe product when used  
10 according to its indications, correct?

11 A. I think that we have over 3,000 clinical  
12 trials involving tens of thousands of women with data  
13 collected out to seven years that more than adequately  
14 supports the use of Prolift for the treatment of  
15 prolapse in women as an effective product, correct.

16 Q. But you don't know why the defendant  
17 pulled the product, if that's the case, correct?

18 MR. SNELL: Form, foundation, asked and  
19 answered.

20 THE WITNESS: I'm assuming like much in  
21 life, it was a business decision. They  
22 balanced potential revenue versus whatever  
23 investments, and but no.

24 BY MR. SCHNIEDERS:

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1 Q. It was a money decision?

2 A. I don't know.

3 MR. SNELL: Same objection.

4 THE WITNESS: I don't know, sir. I'm  
5 sorry.

6 BY MR. SCHNIEDERS:

7 Q. We've established in the six to eight  
8 procedures per week, at least several of them are going  
9 to involve the products that you are testifying in this  
10 litigation?

11 A. That is correct.

12 Q. So take me through when you have a woman  
13 that comes in with pelvic organ prolapse and you've  
14 determined that Gynemesh PS would be a suitable  
15 surgical placement for her, what do you tell her about  
16 the risks and benefits?

17 A. Specifically, the discussion is the  
18 same. Women with prolapse have a certain set of  
19 baseline symptoms. Obviously, they have both symptoms,  
20 they frequently have bladder or bowel dysfunction. The  
21 majority of them have pre-existing sexual dysfunction.  
22 We explain to them the intent and the limitations of  
23 surgery in general in correcting those problems. I try  
24 to set realistic expectations as far as what is likely

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1 to get better, what may not get better, and then we  
2 start to go through their options.

3 As I go through their options, I try to, in a  
4 fairly nondirective manner, to guide them to a decision  
5 based very much on the information that we're reading  
6 in my report. You know, these are the different  
7 procedures at our disposal. These are the different  
8 approaches. Some of these approaches may include  
9 hysterectomy or not hysterectomy. Some may involve  
10 simple tissue plication. Some are done abdominally,  
11 some are done vaginally, some are done as a combination  
12 of both. Some may involve the placement of mesh  
13 surrounding the vagina, and we go over what these  
14 women's priorities are, what their concerns are, what  
15 they hope to accomplish. We look at their ages, their  
16 co-morbidities, and I try to help them on an individual  
17 level to make a decision that's best for them.

18 Q. And on the topic of mesh and more  
19 specifically Gynemesh PS comes up, what do you tell  
20 them the risks are of that procedure?

21 A. Again, the conversation is largely, you  
22 know, all prolapse surgery come with very similar risks  
23 in terms of whether or not it will be successful,  
24 whether or not you will develop normal bladder

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1 emptying, abnormal bladder emptying, could you  
2 experience chronic pain, could you experience pain with  
3 sexual intercourse. I can't tell you that I -- you  
4 know, I don't necessarily distinguish from one to the  
5 other in a general sense.

6 Obviously, if we're going to implant mesh, I  
7 speak to them about the fact that polypropylene mesh is  
8 the most widely used material in our field, that  
9 there's experience that goes back decades. That, in  
10 general, this is the consensus standard of care  
11 material used throughout the world, and obviously we  
12 talk to them a little bit about our personal experience  
13 in our practice and over my 24, 25 years of clinical  
14 practice.

15 Q. So when you're talking to a woman about  
16 placement of Gynemesh PS, do you tell her that it's  
17 possible that she will have chronic pain following the  
18 surgery?

19 A. To be honest with you, we rarely see  
20 pain as a consequence of these procedures. I certainly  
21 will say that there's always the potential for pain.  
22 Again, I don't believe that it's the mesh itself. To  
23 be honest with you, most of the pain that we see is  
24 certainly more related to the plication parts of the



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1 procedure.

2 Rarely do I think the mesh has anything to do  
3 with that. You know, I think certainly if you look at  
4 the report, counselor, vaginal length tends to be  
5 longer when we use the mesh, sex tends to be more  
6 comfortable when we use the mesh. The incidence of  
7 pain is no higher than it is with the other techniques.  
8 The incidence of dyspareunia in most studies is  
9 extremely low, you know, certainly 10% is the summary  
10 incident that we will talk about. In randomized  
11 trials, it's been as low as 3%.

12 Native tissue repairs, in my opinion and in the  
13 literature that I've reviewed, often times have  
14 dyspareunia rates that are far higher, 15%, 25%.  
15 Again, it's a complicated discussion. The majority of  
16 these people have some degree of pain with sex prior to  
17 surgery. We have to speak about the likelihood that  
18 that pain will improve. There are some women that have  
19 no pain. We talk about the chance or the rates of de  
20 novo dyspareunia. It's not a black-and-white kind of  
21 discussion, and it's typically a discussion that takes  
22 place over three or four visits.

23 MR. SCHNIEDERS: I will object and move  
24 to strike as nonresponsive.

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1 BY MR. SCHNIEDERS:

2 Q. Doctor, when you are talking to a women  
3 about placement of Gynemesh PS, do you tell her it's  
4 possible that she will have chronic pain following the  
5 surgery?

6 MR. SNELL: Objection. I think he's  
7 asked and answered that.

8 THE WITNESS: Okay. So the Gynemesh is  
9 only one part of the surgical procedure that  
10 I'm doing. So we are talking -- I talk to them  
11 about the overall risk of the surgical  
12 intervention. If we're going to do a  
13 hysterectomy and a sacrocolpopexy with mesh and  
14 a posterior repair, I'm talking about the  
15 overall likelihood of complications.

16 MR. SCHNIEDERS: Mark as Exhibit 10 the  
17 IFU for Gynemesh PS.

18 (Document marked for identification as  
19 Toggia Deposition Exhibit No. 10.)

20 BY MR. SCHNIEDERS:

21 Q. Doctor, are you familiar with this  
22 document?

23 A. I am familiar with the IFU, yes.

24 Q. For the jury's benefit, what does the

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1 IFU tell a doctor?

2 A. The IFU stands for information for use.  
3 It's a document that will explain everything from the  
4 material you use, how it's sterilized what the intended  
5 uses are, situations in which it might be used. There  
6 is a listing of precaution and adverse events that are  
7 known and some suggestions to the surgeon to keep in  
8 mind when the surgeon is coming up with a surgical  
9 plan.

10 Q. And this is the 2015 version of this IFU  
11 because you understand that this IFU is updated  
12 February of 2015, correct?

13 A. That is my understanding, correct.

14 Q. Do you make it a habit as a surgeon to  
15 read the IFUs for all products that you're placing?

16 A. I am pretty much an instruction reader  
17 in general. I even read the instructions to my VCR and  
18 my phone, although, obviously, I missed the part about  
19 the voice speaking, but, yes, I am -- I do read, and  
20 largely, you know, I do teach, so I want to make sure  
21 that what I say is consistent with the IFU.

22 Q. Just excited you still have a VCR.

23 A. I know, right.

24 Q. If you go to the indications, what are

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1 the indications for Gynemesh PS? It's on the second  
2 page.

3 A. With the understanding that as a  
4 surgeon, I've got the ability to use things as I see,  
5 you know, fit for what I'm working on. Specifically,  
6 we use Gynemesh for the correction of pelvic organ  
7 prolapse. What it says here specifically that it's  
8 being used as a bridging material for apical, vaginal  
9 and uterine prolapse. This one here that you've given  
10 me specifically, in my opinion, is referring to an  
11 abdominal approach.

12 Q. Okay. And was Gynemesh previously  
13 indicated for only an abdominal approach?

14 A. My understanding back in 2002, when  
15 Gynemesh -- Gynemesh PS received its indication, it was  
16 not stated in the same language, it was stated in a  
17 much more general sense that it could be used for  
18 prolapse, and the implication was either abdominally or  
19 vaginally.

20 Q. And is it your -- do you have the --  
21 strike that.

22 Are you aware that that indication was changed  
23 at the same time that Prolift was removed from the  
24 market?

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1           A.       I'm aware through my review of these  
2 materials. I can't tell you at the specific moment  
3 that it was removed from the market that I was abruptly  
4 aware of that.

5           Q.       So there wasn't an Ethicon rep that was  
6 coming by your office to let you know?

7           A.       I mean, in general, I'm an expert in  
8 this area. I possess far more expertise than  
9 representatives. I can't tell you that I really depend  
10 upon the sales rep, in general. I know most things way  
11 before and beyond what any of the sales reps, so I  
12 cannot tell you that I have -- you know, that that's  
13 a -- where I depend upon the information from.

14          Q.       But fair to say that the IFU is a  
15 document that's intended to give surgeons additional  
16 information about a product, including safety  
17 information, correct?

18          A.       It's a document that provides guidance.

19          Q.       If you go to the third page under  
20 adverse reactions, and I can mark the other IFU, if you  
21 like, Doctor, but if you have a recollection, do you  
22 recall that -- well, actually, let's just do it this  
23 way.

24                   Strike that.

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1 (Document marked for identification as  
2 Toglia Deposition Exhibit No. 11.)

3 BY MR. SCHNIEDERS:

4 Q. I'm marking as Exhibit 11 the previous  
5 IFU for Gynemesh PS, although I apologize that it's got  
6 a lot of other languages in there along with it. But  
7 the English version should be right out front.

8 So, Doctor, if you go to what we've marked now  
9 as Exhibit 11, that is the version of the IFU for  
10 Gynemesh PS that was in effect previous to this  
11 February of 2015.

12 Does that look consistent with your  
13 recollection?

14 MR. SNELL: Give me a second to look at  
15 it. Okay. Go ahead.

16 THE WITNESS: Sure. The date on here is  
17 September 15, 2008. I agree with you that this  
18 one preceded this one.

19 BY MR. SCHNIEDERS:

20 Q. If you look at the second page, would  
21 you look at the indication there for Gynemesh PS as of  
22 2008?

23 A. Yes, I do see that paragraph.

24 Q. And that's a different indication than

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1 what is in place in February of 2015, correct?

2 MR. SNELL: Foundation.

3 THE WITNESS: I would say the  
4 indications to me seem similar. The wording  
5 has been changed. In both they mention that  
6 the material is used for bridging material for  
7 the treatment of prolapse. One mentions  
8 vaginal wall. The other one is more inclusive  
9 of apical, vaginal and uterine. So, I mean,  
10 the language is slightly different. My opinion  
11 is the intent is pretty much the same.

12 BY MR. SCHNIEDERS:

13 Q. But the previous version of the IFU  
14 didn't infer an abdominal approach, correct?

15 A. Correct.

16 Q. Whereas the February 2015 IFU does,  
17 correct?

18 A. Correct.

19 Q. Okay. Doctor, if you go to the third  
20 page of both IFUs, you'll find the section that's  
21 called adverse reactions, and you can see just by  
22 looking at it at first glance, that the adverse  
23 reactions section in 2015 is much longer than it was in  
24 the previous version, correct?

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1 A. Yes.

2 Q. And under -- in the previous version it  
3 states potential adverse reactions are those typically  
4 associated with surgically implantable materials,  
5 including infection, potentiation, inflammation,  
6 adhesion formation, fistula formation, erosion,  
7 extrusion and scarring that results in implant  
8 contraction.

9 Did I read that correctly?

10 A. Yes, you did.

11 Q. And that's the only thing that's listed  
12 under adverse reactions in the previous IFU, correct?

13 A. Yes.

14 Q. If we go to the more recent IFU, I  
15 believe that that bullet point essentially that I just  
16 read with a few additional terms appears as the first  
17 bullet point in adverse reactions.

18 Does that look like a fair reading?

19 A. I agree.

20 Q. And then there's several -- there's  
21 eight more bullet points that follow in adverse  
22 reactions, correct?

23 A. Yes.

24 Q. And I missed two. There's two more on



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1 the next page as well, so ten more, correct?

2 A. Yes.

3 Q. Okay.

4 A. Well, and then there are other adverse  
5 reactions, but I'm with you, counsel. I'm following  
6 along with you.

7 Q. Okay. So that second bullet point there  
8 that starts with "as with any implants," could you read  
9 that, Doctor.

10 A. As with any implant, a foreign body  
11 response may occur. This response could result in  
12 extrusion, exposure -- excuse me -- erosion, exposure,  
13 fistula formation and/or inflammation.

14 Q. And the third bullet point there that  
15 begins with "potential adverse reactions," could you  
16 read that?

17 A. Potential adverse reactions are those  
18 typically associated with pelvic organ prolapse repair  
19 procedures, including pelvic pain, pain with  
20 intercourse, which in some patients may not resolve.

21 Q. If you go to the bullet point that  
22 begins with "excessive contraction," could you read  
23 that, Doctor.

24 A. "Excessive contraction or shrinkage of

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1 the tissue surrounding the mesh, vaginal scarring,  
2 tightening and/or shortening may occur."

3 Q. And what would happen if there was  
4 excessive contraction or shrinkage of the tissue  
5 surrounding the mesh?

6 A. I guess it would vary, depending upon  
7 where specifically we were talking about that.

8 Q. As the expert here, Doctor, tell me what  
9 are the different alternatives.

10 A. As the expert I can tell you I've never  
11 observed shortening or shrinking or scarring, but,  
12 again, I'm speaking to, you know, in the anterior  
13 compartment, there could be some influence on bladder  
14 function. At the apical end of things, I would think  
15 that it could affect sexual intercourse. In the  
16 posterior compartment, there could be events there,  
17 although, again, I point out in my report, I evaluated  
18 this extensively, and there's no evidence from the  
19 literature that these types of events are occurring  
20 with any greater frequency with these products as  
21 compared to other types of repairs, and that is  
22 inferred in the paragraph I believe that you read  
23 yourself, that these are risks typically associated  
24 with pelvic organ prolapse repair.

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1 Q. Actually, that's the first paragraph.

2 A. Sorry. Third bullet point, "Potential  
3 adverse reactions are those typically associated with  
4 pelvic organ prolapse repair procedures."

5 Q. And obviously excessive contraction or  
6 shrinkage of the tissue surrounding the mesh, vaginal  
7 scarring, tightening and/or shortening is not something  
8 that is caused by pelvic organ prolapse, correct?

9 A. Pelvic organ prolapse or pelvic organ  
10 prolapse repair procedures?

11 Q. Fair enough. The repair procedure.

12 A. It is, and, again, if you read through  
13 my report, these are common adverse events that are  
14 associated. That's why it says that. It says  
15 potential reactions and it says typical, not unusual,  
16 typically associated with pelvic organ prolapse repair  
17 procedures. And, again, I have cited several very  
18 reputable sources analyzing over 100 studies involving  
19 10, 11,000 patients suggesting low incidence of these  
20 things and incidences that are not any different than  
21 what is typically associated with pelvic organ prolapse  
22 repair that does not involve mesh.

23 Q. Regardless of whether it's caused by  
24 pelvic organ prolapse repair or by the mesh, you've

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1 never seen it either way, right?

2 A. That's not what I've said, sir. I said  
3 that, in my experience, as I stated in my report, I've  
4 never seen the mesh cause shrinkage or scarring above  
5 or beyond what we would typically see.

6 Q. Do you see the second to last bullet  
7 point that says "neuromuscular problems, including  
8 acute and/or chronic pain in the groin, thigh, leg,  
9 pelvic and/or abdominal area may occur"?

10 A. I do see that.

11 Q. Do you agree with that statement?

12 A. I agree, yes, that with pelvic organ  
13 prolapse repair procedures that we do that those  
14 problems can occur. They can occur with suture based  
15 repairs. They can occur with mesh based repairs. If I  
16 could refer you to the study, and I'm sorry, some of  
17 these names I have trouble pronouncing, he did  
18 sacrospinous ligament suspension, Qataweh, okay, he  
19 points out, for example, temporary sciatic neuralgia,  
20 this is on Page 15 of my report, pointed out that about  
21 I believe it was 11% of patients in either group  
22 experienced sciatic neuralgia.

23 Actually, Barber et al. in what's the OPTIMAL  
24 trial, and the OPTIMAL trial is included in the

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1 materials I provided for you, and these were suture  
2 based repairs, nerve pain was observed in one arm,  
3 6.9%, in the second arm 12.4%.

4 Q. Okay. In your risk-benefit discussion  
5 with a patient who is potentially going to have a  
6 Gynemesh PS placed, do you tell her that excessive  
7 contraction or shrinkage of the tissue surrounding the  
8 mesh, vaginal scarring, tightening and/or shortening  
9 may occur?

10 A. Again, we don't do these procedures in  
11 isolation, so I speak to them about the total  
12 procedure. In general, that's not been our experience  
13 to see that, but I do explain to them that sometimes  
14 surgery can result in pain, either pain during sex or  
15 even pain not related to sex. And, obviously, they  
16 have an incision in the vagina. It's -- the incision  
17 is obviously going to be tender initially. That  
18 tenderness usually resolves over time; however, there  
19 are instances in which the pain will persist. I don't  
20 specifically say it's the product that causes those  
21 procedure because based upon the records -- excuse me,  
22 the literature that I have reviewed and my own personal  
23 experience in 25 years, that has not been what we have  
24 observed or is what's been reported.

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1           Q.       Do you tell that woman that potentially  
2   is going to have Gynemesh placed that neuromuscular  
3   problems, including acute and/or chronic pain in the  
4   groin, thigh, leg pelvic and/or abdominal area may  
5   occur.

6           A.       I think that's what we just address, in  
7   general I tell them that is part of the risks of  
8   surgery in general for pelvic organ prolapse, that they  
9   are uncommon problems, and, again, if it's a patient  
10   with fibromyalgia, they probably have a little bit  
11   higher risk because they're already sort of predisposed  
12   to that. Again, it may vary based upon age. So it's  
13   really a general discussion that is sort of tuned for  
14   that individual, but, overall, I am covering the  
15   general topics as listed in -- that we've just been  
16   discussing from the IFU.

17          Q.       But your discussion with women that are  
18   undergoing surgery to correct pelvic organ prolapse is  
19   the same, regardless of whether you're placing a mesh  
20   or you're doing any other surgery, correct?

21          A.       Yes, because the risks are the same.  
22   Incidence of dyspareunia, pain, defecatory dysfunction,  
23   voiding dysfunction, incontinence, in general is not  
24   different percentage-wise between the procedures, and

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1 that is sort of the sum and basis of the report that  
2 I've generated for this purpose.

3 Q. Do you tell a woman that potentially is  
4 to receive a Gynemesh PS product that at some point  
5 another surgeon or you may have to go in there and  
6 remove the mesh?

7 A. In general, I inform the woman that the  
8 mesh is permanent, that the good news is is that,  
9 typically, if we get a satisfactory result, that result  
10 is long lasting. I explain to them that typically the  
11 literature has supported that repairs done with mesh  
12 are typically superior to the results without mesh, and  
13 that certainly has matched our personal experience in  
14 this field in the last 25 years, but, yes, if they were  
15 to develop pain that there may be a risk of  
16 re-intervention. Typically, that risk of  
17 re-intervention is low in our practice. It's probably  
18 5%.

19 The literature would suggest that the risk of  
20 re-intervention is in the low teens, again, depending  
21 risk factors. What's the patient's age, is she a  
22 smoker, is she obese. So sometimes I do fine-tune that  
23 and say I would consider you to be somebody at a little  
24 bit higher risk than what I'm explaining to you right

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1 now or somebody that I believe are a little bit lower  
2 risk, but, again, it's always part of that general  
3 discussion about the surgery in general because we  
4 rarely go in and just sort of do one thing and nothing  
5 else.

6 Q. But it's fair to say that if mesh is  
7 never placed, that you don't have to go in and remove  
8 mesh if there's a complication, correct?

9 A. If mesh is not placed, then you don't  
10 have to go in to remove mesh. If suture is placed, you  
11 may have to go in to remove sutures, and, again, in our  
12 experience, those occur with equal likelihood.

13 Q. With sutures there's equal likelihood  
14 that another intervention would be necessary?

15 A. Correct. In fact, I published a paper  
16 in which the likelihood re-intervention to remove  
17 sutures exceeded 30%, and that is certainly -- that is  
18 probably three times the incidence of us having to go  
19 back to deal with mesh-related wound -- I'm just going  
20 to classify these are all types of wound complications.  
21 So whether the wound opens up, whether there's a suture  
22 that's exposed, whether the wound opens up and mesh is  
23 exposed, that's a wound complication.

24 In our practice and supported by the



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1 literature, they occur at least with equal frequency.  
2 In our hands, they occurred three times higher with  
3 suture based repairs.

4 Q. Did you ever approach Ethicon and ask  
5 that Gynemesh's mesh be less rigid?

6 A. I don't know. I'm concerned because you  
7 seem to be reading from something while you're asking  
8 me that question, but I honestly don't know. I'm sure  
9 I offered them opinions, again, in a theoretical sense  
10 whether it was Prolift+M, whether it was Prolift,  
11 whether it was Gynemesh, there were subtle variations,  
12 there were other products from other companies, I may  
13 have had ideas about what I thought.

14 I mean, my recollection is that I said to them,  
15 look, at least in my observation, I find that, you  
16 know, Prolift+M is a more rigid material. At the time  
17 of implantation, that may be beneficial, it's a little  
18 easier to work with if it's rigid; however, it could,  
19 in fact, maybe be associated with more wound  
20 complications, and I would let them know that just so  
21 they can just include that in the information that  
22 they're receiving.

23 You know, again, I tended to be an early  
24 adopter of these procedures, and I felt a

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1 responsibility as an early adopter to provide early  
2 feedback.

3 Q. What is your understanding of what a KOL  
4 is?

5 A. A KOL is a term that means key opinion  
6 leaders, and it's a term used by industry to identify  
7 people that they considered to be key opinion leaders.  
8 What they specifically mean by that and what I might  
9 think about that may not be the same thing.

10 Q. Would you have considered yourself to be  
11 a KOL for industry?

12 A. I mean, I think they might consider me  
13 to be a KOL. You know, I mean, certainly, at this  
14 point in time, I've been doing this for a long time, I  
15 do a high clinical volume, I'm a relatively  
16 straightforward and approachable person, and I'm pretty  
17 liberal with my opinions, but I would say -- sorry to  
18 give you a long-winded answer, I know that  
19 organizations have considered me to be a key opinion  
20 leader in this area.

21 Q. What is -- in medicine, what's a  
22 conflict of interest?

23 MR. SNELL: Form, overbroad.

24 THE WITNESS: Exactly. You know, I

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1 mean, there are very many different forms of  
2 conflict of interest. I mean, you know, I'd  
3 have to get -- have a specific situation.

4 BY MR. SCHNIEDERS:

5 Q. Well, when drafting an article, is it  
6 part of the canon that physicians will disclose  
7 potential conflicts they might have that could  
8 potentially affect their opinion?

9 MR. SNELL: Form, vague, also undefined  
10 as to scope and time.

11 THE WITNESS: You know, I think there's  
12 a fine line between bias and conflict of  
13 interest, however, you know. For example, in  
14 the TVT Secur trial, I revealed to the  
15 publishing journal and the people reviewing the  
16 manuscript that, you know, yes, I have taught  
17 this procedure and I have been compensated for  
18 that time.

19 I'll tell you, quite honestly, I don't  
20 think the results of that trial was of any  
21 benefit to the company, you know. The company  
22 did not pay for that trial directly. It  
23 involved their products, so my involvement was  
24 based on my experience. My involvement was not

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1           based upon the fact that I had a relationship  
2           with the company, but I understand that some  
3           people might view that as a negative, so I did  
4           disclose that.

5   BY MR. SCHNIEDERS:

6           Q.       Well, what's the purpose of disclosing  
7           conflicts in literature?

8                   MR. SNELL:   Same objection.

9                   THE WITNESS:   You know, I think when you  
10           read something, you're trying to understand  
11           where that person is coming from and whether or  
12           not they may be otherwise motivated.   You know,  
13           if I own stock in a company, I could run around  
14           and say -- you know, if I own stock in  
15           Volkswagen and I drove a Volkswagen, I might  
16           tell Bert and yourself and anybody else what a  
17           great car, I've never driven a better car, and  
18           I own stock in this company because I've got a  
19           conflict, in a sense.   So that's how I would  
20           view a conflict.   I might be otherwise  
21           motivated in revealing that information.

22   BY MR. SCHNIEDERS:

23           Q.       As a physician, when you're reading  
24           literature how do you factor in potential conflicts?

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1           A.       You know, it's just one of a host of  
2 variables. Everybody clearly has a bias, you know, or  
3 a prejudice, you know, many of which might be based  
4 upon personal experience. So, you know, even if  
5 there's no industry related conflict, you know, there's  
6 always bias involved, and it's just one thing to keep  
7 in mind and it's a very -- you have to balance, you  
8 know, that with everything else that you're reading.

9           Q.       And is that something that you as a  
10 reviewer of literature do when you're reviewing  
11 studies, for instance, in this case?

12          A.       We look at their disclosures, you know.  
13 We looked at funding for the study direct. We look at  
14 what the authors would reveal as potential conflicts.  
15 I can't tell you that that is -- that commonly changes  
16 the overall value of the report or what's being said.  
17 The results typically speak for themselves. There are  
18 a number of internal controls.

19               So, for example, when you randomize somebody to  
20 one intervention or the other, you're looking to  
21 minimize bias. When you do a randomized trial that  
22 might involve over 50 surgeons across five different  
23 countries, as had been done, for example, with Prolift,  
24 you will also minimize those biases as well. When

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1 things are blinded to the patient, you're trying to  
2 minimize the bias. If the patient knew that they were  
3 having the same procedure that maybe their sister had  
4 and their sister had a great result, for example.

5 Obviously it's a little harder to blind a  
6 surgeon. You can't blind them to do the actual  
7 procedure, I don't think that would be safe, but  
8 sometimes the person who is doing the evaluation of the  
9 result might be blinded to what the surgeon did. That  
10 was the case, for example, I believe with the TVT Secur  
11 trial, it was sort of single blinded in that regard.

12 Q. Is it significant to you when you review  
13 literature how much money one of the authors might have  
14 made from a company that that study benefits?

15 A. Typically, no.

16 Q. Is there a threshold where it does  
17 become important, for instance, if they make \$500,000?

18 A. I'm not aware -- I don't have a  
19 threshold, no.

20 Q. So not a million dollars?

21 A. I don't have a threshold.

22 Q. \$10 million?

23 A. I don't know how I can say I don't have  
24 a threshold any differently. You know, again, from

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1 where I sit, as you can tell from my report, I'm more  
2 interested in the -- what we call sort of the summary  
3 or the pooled analysis of data. I'm not going to hold  
4 any single study as being the Holy Grail. I'm looking  
5 for consistencies between studies. I'm factoring in  
6 thing like biological plausibility to what's being  
7 offered. I'm looking very specifically at levels of  
8 evidence, you know, reproducibility of the results.  
9 Those are far more important to me than who was paid  
10 what for what and why.

11 Q. Who other than authors of a study should  
12 hold editorial power over the study?

13 MR. SNELL: Form.

14 THE WITNESS: You know, again, all  
15 studies are different. You know, some  
16 studies -- you know, if somebody is paying for  
17 a study to be performed, and, again, that's an  
18 arrangement made between the investigator and  
19 the source of the research, you know, for  
20 example, the NIH if they're going to sponsor a  
21 study, they oftentimes will insist that that  
22 study be available at no cost in a public forum  
23 to anybody who might want.

24 Certainly, in some of these studies that

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1           were directly funded by the company, the  
2           company wanted to have access to those results.  
3           I don't know that it is common for there to be  
4           any undue influence, but, again, that sort  
5           of -- you know, you would think that once a  
6           study was published, it's sort of passed  
7           certain bars of professionalism to get to that  
8           point.

9   BY MR. SCHNIEDERS:

10           Q.       Just so I'm clear because you just said  
11           after published, I'm talking about before it's  
12           published when it's still a draft manuscript?

13           A.       Sure. I'm sorry. What I was saying if  
14           a study becomes published, you would assume this would  
15           have been vetted. It varies, it varies widely, you  
16           know, in our experience, as far as how much influence.  
17           Sometimes it's simply they want to be aware of the  
18           data. You know, sometimes they may want to contribute  
19           information. I'm not sure exactly what you're  
20           implying.

21           Q.       I'm just asking is it appropriate for a  
22           pharmaceutical or a device company to have a draft copy  
23           of a study and add or subtract words from it prior to  
24           it being published?



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1 MR. SNELL: Objection, vague, lacks  
2 foundation, incomplete hypothetical.

3 THE WITNESS: I think if -- I think that  
4 typically that is an agreement and a decision  
5 that is made before the study actually begins  
6 and, therefore, is kind of sort of removed from  
7 the actual results of the study, so it varies  
8 widely. You know, as an investigator you have  
9 to decide your level of comfort of that  
10 involvement.

11 You know, you appear to be maybe too  
12 young to have children in college, but it's the  
13 same argument, if I'm paying for my son to go  
14 to college, do I deserve to know, you know, his  
15 shenanigans, his grades, potential issues, you  
16 know. Again, there are agreements between you  
17 and your child, between you and the school,  
18 same thing in here. But those are usually  
19 clearly defined at the time that there's an  
20 agreement to fund the study and it varies.

21 BY MR. SCHNIEDERS:

22 Q. In your study that was funded by  
23 Ethicon, did they have editorial control?

24 A. My study was not funded by Ethicon.

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1 Q. It wasn't?

2 A. Not directly, no.

3 Q. What do you mean "not directly"? That  
4 sounds like a qualifier.

5 A. My study was not -- again, I was not the  
6 study designer, but the study was funded by -- the  
7 funding is listed on the actual study, I believe it was  
8 the foundation, and I'm sorry if I'm forgetting the  
9 exact terms, the foundation of women's health. I did  
10 not receive any compensation, and I don't -- it was  
11 founded by the foundation, and it was a randomized  
12 study between seven sites. So I would violently object  
13 to you telling me that that study was funded by Ethicon  
14 because it was not.

15 Q. And not sure if I'm clear, are you  
16 saying you didn't get compensated at all for that  
17 study, or you didn't get compensated by Ethicon?

18 A. I was not compensated by Ethicon for  
19 that study.

20 Q. But the foundation, they compensated  
21 you, right?

22 A. The -- excuse me, the study compensated  
23 my practice for the data collection and the clinical  
24 nurse coordinator and stuff like that.

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1 Q. Did you get paid anything yourself?

2 A. I mean, in my employment all monies go  
3 into a pool. We subtract expenses from revenue. The  
4 money doesn't come to me directly labeled or traceable  
5 from any one site.

6 Q. So, clearly, if Ethicon didn't fund your  
7 study, it would be inappropriate for them to have a  
8 draft copy and make edits on that, right?

9 A. Those are two completely separate  
10 issues.

11 Q. How so?

12 MR. SNELL: Objection, asked and  
13 answered.

14 THE WITNESS: Again, I was not part of  
15 the -- that discussion. I did not discuss the  
16 study with Ethicon. I don't -- was not part of  
17 that discussion. My understanding is that they  
18 saw a copy of the results. I do not believe  
19 that they had any influence. I will tell you  
20 that that particular study won two first prizes  
21 as best surgical paper of the year, both one  
22 nationally, one internationally. That is not  
23 something that occurs with an industry -- you  
24 know, an industry sponsored study.

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1 BY MR. SCHNIEDERS:

2 Q. So that was not an industry sponsored  
3 study, correct?

4 A. Again, I was not -- I did not design the  
5 study. I am not employed by the foundation that I  
6 mentioned, so that was not directly funded by Ethicon.  
7 The foundation collects money from various sources,  
8 including people like myself that would make a  
9 contribution. The pooled resources of the foundation  
10 funded studies. The studies were designed by the  
11 investigators. The company had no influence on the  
12 study design. The company had no influence on the  
13 study results. The company had no influence on the  
14 writing of the manuscript and they certainly had no  
15 influence in the presentation or the submission of the  
16 data. I hope I've clarified that for you because you  
17 seem to be a little misinformed in that regard.

18 (Document marked for identification as  
19 Toggia Deposition Exhibit No. 12.)

20 BY MR. SCHNIEDERS:

21 Q. Doctor, I'm showing you what I'm marking  
22 as Exhibit 12, which is a PowerPoint that came from  
23 Ethicon and it's entitled "KOL Strategy."

24 A. Uh-huh.

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1 Q. So a moment ago when we were talking  
2 about KOLs, we discussed the fact that that means key  
3 opinion leader within the industry, correct?

4 A. That's my assumption. I can't tell you  
5 that anyone has ever -- I've kind of figured that out  
6 myself. Obviously, it doesn't stand for Knights of  
7 Columbus, but I'm assuming that that's what that means.  
8 I have no objection if you tell me that that's what  
9 that means.

10 Q. That's my understanding as well.

11 If you see on the front page of this, this is  
12 from February of 2008, you see that?

13 A. And this is coming specifically from  
14 where?

15 Q. This is from Ethicon.

16 A. But where specifically within Ethicon?  
17 This is marketing, this is R&D, this is --

18 Q. We would have to get the Bates number  
19 and tell you whose file it was in, but it's from one of  
20 their internal files.

21 A. Sure.

22 Q. So if you go to the third page --  
23 probably marketing, typically.

24 A. I would agree with that. I'm sorry that

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1 I led you to that statement.

2 Q. Typically, KOLs work with marketing,  
3 right?

4 A. I mean, I was a KOL that worked -- like,  
5 my involvement, say, with Astellas, which is more  
6 Astellas global international, my involvement is not  
7 marketing. It's more R&D, and, you know -- and as  
8 we've been discussing, much of my relationship and  
9 interest with Ethicon has been R&D.

10 Q. So if we got to this third page that  
11 says "KOL Categorization," there's a circle with  
12 several other circles surrounding it?

13 A. Yes.

14 Q. It starts off it's got the KOL here in  
15 the middle in the blue circle, and then it's got all  
16 these different categories, it appears, that whoever  
17 put this PowerPoint together feels fall within that KOL  
18 categorization.

19 You see that?

20 A. Yes.

21 Q. And there's things like society or  
22 influencer, expert user, advocacy/PR, faculty. Are  
23 those all things that you've seen in other KOLs that  
24 were with Ethicon as well as you?

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1 MR. SNELL: Foundation.

2 THE WITNESS: You know, I got to be  
3 honest with you, I was not someone that was,  
4 you know, involved at all levels. I did my  
5 little piece and stuck to my little piece. To  
6 me, I look at this, and I'm like, what is a  
7 KOL? Well, a KOL could be any of these things,  
8 or all of these things would contribute to a  
9 KOL. You know, some of these people could be  
10 physicians, advocacy, could be some of these  
11 advocacy groups that are out there, the  
12 incontinence -- National Incontinence Society.

13 BY MR. SCHNIEDERS:

14 Q. Do you consider AUGS to be an advocacy  
15 group?

16 A. AUGS is an advocacy group, yes.

17 Q. If you go to next page, there is a title  
18 that says "Objective," and there it says, "Engage KOLs  
19 across the spectrum of functional expertise to partner  
20 with EWH&U in supporting organizational objectives."

21 Did I read that correctly?

22 A. You did.

23 Q. And EWH&U stands for Ethicon, correct,  
24 women's health?

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1           A.       It stands specifically for Ethicon  
2    women's health and urology.

3           Q.       So the group putting this together at  
4    Ethicon feels that KOLs can be brought in in order to  
5    support organizational objectives, correct?

6                   MR. SNELL:   Calls for speculation.

7                   THE WITNESS:   Again, you know, my  
8                   role -- and, again, my role as a KOL person of  
9                   influence was infinitesimal. I was not as --  
10                  as they would say, I was not in the starting  
11                  lineup. You know, I take it for what it reads,  
12                  that the objective of this project was to  
13                  engage KOLs across the spectrum, meaning that  
14                  we're not just going to focus on surgeons, you  
15                  know, we're just not going to focus on  
16                  inventors. We're looking for a broad range of  
17                  individuals that might be able to help us.

18   BY MR. SCHNIEDERS:

19           Q.       If you keep going, skip the next page,  
20    next two pages actually and there should be something  
21    that says "Categories" at the top. There you go.

22           A.       Yes.

23           Q.       And it's got several different  
24    specialities, for lack of a better term.



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1 A. Sure.

2 Q. The top one is "Incontinence/Pelvic  
3 Floor Specialist (UroGyn, GYN)," and of these groups,  
4 and you can look at it, by all means, but that's  
5 probably the group that you would identify most  
6 specifically with, right?

7 A. Yes.

8 Q. If you go to the next page, it starts  
9 off with -- it's got a title, it says "Incontinence  
10 (UroGyn, Gyn)," and then it's got different categories,  
11 as you can see, in the top. It's got "Prof Ed  
12 Faculty," which is professional education, right?

13 A. Yes.

14 Q. And under that it says "National TVT  
15 Preceptor," and you're at one point a national TVT  
16 preceptor, weren't you?

17 A. Yes, I do believe that I was categorized  
18 as a national preceptor.

19 Q. And there's a category called  
20 "Published," and under that it says "Published in peer  
21 reviewed journals." Is that read correctly there?

22 A. I'm sorry. I was looking at a different  
23 page, and I apologize for not paying attention.

24 Q. So right next to Prof Ed, there's a

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1 category called "Published."

2 A. Yes.

3 Q. And under that it says -- under where it  
4 says "Description/Criteria," it says "Published in peer  
5 reviewed journals." Did I read that right?

6 A. Yes.

7 Q. And then if you go all the way, there's  
8 "Academic" and then there's "Inventor."

9 A. Yes.

10 Q. And there's "Emerging," and then there's  
11 "Expert User."

12 A. Okay.

13 Q. And "Description/Criteria" is "High  
14 utilization of product (EWH&U and Competitive)."

15 Did I read that correctly?

16 A. Yes.

17 Q. Okay. And what does that mean to you as  
18 far as high utilization of product?

19 A. My interpretation is given that this was  
20 a marketplace that had 49 slings, my interpretation is  
21 that if 99% of what you did in this sphere was with our  
22 product, as opposed to I dabbled with everybody's  
23 product, I would interpret that to mean, you know, that  
24 that's where high utilization.

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1 Q. And then there's "Advocacy/PR/Policy"  
2 and the criteria there is "Practice in top 25 media  
3 market, academic/society affiliation," and last one is  
4 "Society Leadership or Influencer, leadership role in  
5 AUA, AUGS SUFU" --

6 A. Sure.

7 Q. "AAGL, ACOG, General Influencer."

8 A. Uh-huh.

9 Q. If you go to the next page, then it puts  
10 some names here with the group. I'm sure you're  
11 shocked by that.

12 A. I have no vested interest and could care  
13 less. This is their opinion. It means nothing to me.  
14 I could care less where -- I'm just laughing as far as,  
15 you know, they have me listed as an inventor, you know.

16 Q. They do?

17 A. Yeah, see that.

18 Q. They have you listed under inventor  
19 actively engaged in the creation of new products?

20 A. Right. How come I'm not in the top ten?

21 Q. And then -- well, you are in the top ten  
22 on several of these.

23 A. No, I'm not. Not on this one I'm not.  
24 This is TVT.

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1 Q. Under "Expert User, High utilization of  
2 product," you're actually in bold there, if you see  
3 that down at the bottom?

4 A. I have no idea what that means. I'm  
5 actually on that list twice.

6 Q. You are, you are.

7 A. Yes, I don't know. I mean, again, I  
8 don't know how to interpret this, in all fairness.  
9 Competitive in my mind is, you know, maybe Boston  
10 Scientific would be interested in this person, so this  
11 is somebody that, you know, other people might be of  
12 interest. That's how I would look at competitive.

13 High utilization, I mean, you know my history  
14 with the company, I've used their products extensively,  
15 more so than any other things. So to me that speaks to  
16 the fact that I was an early adopter, and I've remained  
17 engaged throughout that period of time. That's how I  
18 look at it.

19 Q. And if you look at this across the way,  
20 then you'll see that there's probably some names that  
21 are very familiar to you as well?

22 A. I will tell you almost everybody on this  
23 list is familiar to me.

24 Q. And specifically Vincent Lucente who is

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1 someone that you are a colleague of here in the area,  
2 right?

3 A. Yes.

4 Q. And then I believe that in that same  
5 column there, Mickey Karram was an author along with  
6 you in your study?

7 A. Correct, right.

8 Q. Under academic I think Dr. Iglesia was  
9 an author with you as well?

10 A. Yes.

11 Q. Sokol is that someone that you're  
12 familiar with?

13 A. Well, that's an interesting thing. The  
14 Sokols are twins, and they are both urogynecologists,  
15 and this does not distinguish which Sokol we're talking  
16 about.

17 Q. Both of them happen to be defense  
18 experts in this litigation, so it could be either one  
19 of them.

20 And then if you go across --

21 MR. SNELL: Who for?

22 MR. SCHNIEDERS: I don't know the answer  
23 to that.

24 MR. SNELL: I didn't know that. That's

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1 news to me.

2 THE WITNESS: I'm sorry. Are you  
3 testifying?

4 MR. SNELL: No, he made a statement on  
5 the record, so I want to understand it. I  
6 don't know if Eric and the other Sokol are  
7 experts, whatever.

8 MR. SCHNIEDERS: I can find out for you.  
9 I was told that they were.

10 BY MR. SCHNIEDERS:

11 Q. And then over on the far right, you see  
12 that there are some members of the various advocacy  
13 groups, AUA, AUGS. Do you see over there, do you know  
14 Rebecca Rogers?

15 A. I do.

16 Q. Do you know Dee Fenner?

17 A. I do.

18 Q. Do you know Anton Bueschen?

19 A. I do not.

20 Q. John Barry?

21 A. I do not.

22 Q. Are you a member of AUA?

23 A. I'm not a urologist. I am not.

24 Q. But fair to say that there's many names

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1 on here that you're familiar with and that are  
2 colleagues of yours, correct?

3 A. They are. Again, I don't know the  
4 context. I don't know that this is just simply a list  
5 of people to be aware of. So Rebecca Rogers probably  
6 at the time that this was published was the president  
7 maybe of AUGS. Maybe this is someone that they just  
8 want people to be aware of the names or if they saw  
9 them, they would introduce themselves. Maybe this is  
10 somebody that they were hoping to have a better  
11 relationship with. I think -- I mean, the fact that  
12 they considered me to be an inventor I think they're  
13 being very generous or liberal in how they're -- I  
14 think they're just categorizing people, which is  
15 certainly innately human to take things and put them  
16 into nice little boxes.

17 Q. Interesting. But as of February of  
18 2008, you had done some consulting with Ethicon, hadn't  
19 you?

20 A. I had, yes.

21 Q. And if you go there's several pages of  
22 these types of categories, the one I was reading off of  
23 was "Incontinence." The next one is "Incontinence  
24 (Urologist)," and then after that there's a section

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1 called "Pelvic Floor Specialist," which is also a  
2 specialty that I believe you would probably hold  
3 yourself out as holding, correct?

4 MR. SNELL: Form.

5 THE WITNESS: You know, I mean, the  
6 specialty has gone by many names. I think here  
7 they were trying to be inclusive, you know, of  
8 urology, at the time what we called  
9 urogynecology, colorectal, perhaps.

10 BY MR. SCHNIEDERS:

11 Q. But if you look at the page where you'll  
12 have some names that are pelvic floor specialists on  
13 the next page from where you are, I believe, you made  
14 the list. You're an expert user down there?

15 A. I am. Where am I? Oh, there we are.

16 Q. Third from the bottom down there.

17 A. It's a miss -- I don't know who  
18 Dr. Tolia is, but that could be me.

19 Q. I think it's you.

20 A. I would not object to that.

21 Q. And do you know a Dr. Fagan?

22 A. He was my partner.

23 Q. That would make a lot of sense.

24 A. Yeah.



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1 Q. And then there's some other names that  
2 we saw on the other page, but then there's a couple new  
3 ones under "Published" and "Academic." You see a  
4 couple that are Goldman.

5 You see that?

6 A. On the same page?

7 Q. On the same page. If you go to  
8 "Published," the second -- sorry, the third name down  
9 and on "Academic" is Goldman?

10 A. Yes.

11 Q. Do you know Howard Goldman?

12 A. I do.

13 Q. Howard Goldman was one of the authors of  
14 the AUGS mesh statement, correct?

15 A. I will accept that if you tell me that,  
16 yes. I don't have a visual picture of the author list.

17 Q. And just so --

18 A. Are we certain that that's the same  
19 Goldman? It's fairly common.

20 MR. SNELL: How about object,  
21 foundation. Go ahead and lay that for me.

22 BY MR. SCHNIEDERS:

23 Q. So to spell it out for all of you, my  
24 next question on the next page under "Expert User,"

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1 it's spelled out as Howard Goldman. What is the group  
2 CCF? Do you know what the group CCF is?

3 A. I can guess. I can't tell you that I  
4 recognize those initials.

5 Q. Well, I'm not going to hold you to it.  
6 I'm just curious, can you guess for me?

7 A. My guess would be Cleveland Clinic  
8 Foundation.

9 Q. And does Howard Goldman work at  
10 Cleveland Clinic?

11 A. I believe so.

12 MR. SNELL: Can we take a break in a  
13 minute?

14 MR. SCHNIEDERS: I'm switching topics,  
15 so let's take a break.

16 (Brief recess taken at 5:02 p.m.)

17 (Deposition resumes at 5:12 p.m.)

18 BY MR. SCHNIEDERS:

19 Q. I'm going to mark as Exhibit 13 an  
20 e-mail chain that you were included on, Doctor.

21 (Document marked for identification as  
22 Toggia Deposition Exhibit No. 13.)

23 BY MR. SCHNIEDERS:

24 Q. Do you recall earlier when we were

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1 discussing the concept of whether or not funding from  
2 industry or other funding might lead to a conflict of  
3 interest.

4 Do you recall that discussion?

5 A. I do.

6 Q. Okay. You can take a minute, if you  
7 want, to read that bottom e-mail so you have some  
8 context here, and I'm going to ask you if you recall  
9 this?

10 A. I mean, I'm aware of the -- you know,  
11 the discourse between two of my colleagues. Are you  
12 asking me specifically am I aware of the e-mail or just  
13 of the circumstances?

14 Q. Either one.

15 A. I'm aware of the circumstances. I don't  
16 recall whether this was covered in the TVT deposition  
17 or not.

18 Q. You guys covered a lot of stuff that  
19 never made it to the record, and that's impressive.

20 You were on this e-mail?

21 A. Well, I was copied on this e-mail, okay,  
22 right.

23 Q. Right. And what, to your knowledge, was  
24 this consternation about?

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1           A.       If I remember correctly, and this, of  
2       course, is going back for six years, and this is a  
3       relatively minor issue that I think Dr. Iglesias had  
4       either responded in a letter to the editor, it could  
5       have even have been -- you know, when we present things  
6       at national meeting, we allow people to get up, make  
7       comments, suggestions. So in one of these forums, she  
8       was trying to -- and I can't remember which way it  
9       went, whether it was Lucente initially commenting to  
10      Iglesias on her work or whether it was Iglesias  
11      commenting to Lucente, but all I can tell you is that I  
12      recall that there was some friction and really just  
13      collegial -- or not collegial, but discourse between  
14      two colleagues about that interaction.

15           Q.       Fair to say that Dr. Iglesias inferred  
16      that Dr. Lucente's superior outcomes were perhaps due  
17      to financially driven bias?

18                   MR. SNELL: Objection, calls for pure  
19      speculation what somebody else thought.

20                   THE WITNESS: I don't know. I'm sorry,  
21      but I don't know what study or whether this was  
22      written comments, comments in the cafeteria,  
23      comments with someone on the podium.

24      BY MR. SCHNIEDERS:

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1 Q. Do you know why you would have been  
2 included on this e-mail?

3 A. I don't, no.

4 Q. And Dr. Lucente is a colleague of yours.  
5 Do you consider him to be a friend as well, or is it  
6 somewhere in that blurred line?

7 A. I think it's fair to say that -- I've  
8 known Vince since he was a fellow, so we go back at  
9 least 25 years. Vince is certainly both a colleague  
10 and a friend of mine, as is Dr. Iglesias, who I've  
11 known for about the same amount of time as well, I knew  
12 her when she was a fellow as well.

13 Q. Fair enough. Set that to the side.

14 A. You understand that Dr. Lucente and I  
15 are both Italian, and so sometimes that may influence  
16 the tone in which we respond to other people, and we're  
17 both from New York.

18 (Document marked for identification as  
19 Toggia Deposition Exhibit No. 14.)

20 BY MR. SCHNIEDERS:

21 Q. Give you what's been marked as Exhibit  
22 14. Unfortunately, this is the method by which we get  
23 this information a lot of times. I want you to look at  
24 this, and I'll give you an opportunity if you need to

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1 vet it in any way, shape or form as I go through some  
2 of these, but I will tell you if I found one that's a  
3 duplicate, but this is a report that was given to us as  
4 part of a larger spreadsheet and it's been reduced just  
5 down to your name instead of the thousands of columns  
6 and everything like that, and it shows that from  
7 March 1st of 2008 through February 2nd of 2010 that  
8 Ethicon paid you \$152,000.

9 Do you have any reason to dispute that?

10 MR. SNELL: I'm going to object. That  
11 is purely without foundation. You're making a  
12 bald-faced assumption based on contract  
13 amounts. Do not make a statement on the record  
14 that Ethicon paid him that amount of money  
15 without proper foundation. And this was  
16 explicitly covered in the first deposition too.

17 MR. SCHNIEDERS: I've got several of  
18 these.

19 MR. SNELL: You know how much he was  
20 paid. You know how much he was paid. You have  
21 the productions of how much he was paid.

22 MR. SCHNIEDERS: I have this.

23 MR. SNELL: No, no, no. You have the  
24 productions of how much he was paid in each

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1 year.

2 MR. SCHNIEDERS: Make your objections.

3 MR. SNELL: Don't make a ridiculous --  
4 lacks foundation.

5 MR. SCHNIEDERS: Then make the lacks  
6 foundation objection.

7 THE WITNESS: I don't -- I never  
8 received \$81,000 from Ethicon in any given  
9 year. If I looked at this, I would say it's  
10 more like the number to the far left. I mean,  
11 I don't know what the two columns mean, but to  
12 be honest with you, and we did cover this in  
13 the other deposition, you know, the most I ever  
14 got paid from Ethicon in a given year might  
15 have been \$31,000, but, no, \$81,000 no;  
16 \$45,000, no.

17 BY MR. SCHNIEDERS:

18 Q. Okay. So this is incorrect, this  
19 spreadsheet?

20 A. I don't know what this represents, so  
21 how do I say if it's correct or incorrect. I just see  
22 numbers on a page. I don't -- and I'm being very  
23 honest with you, that does not resemble anything in my  
24 working memory.

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1 Q. Okay. So, sitting here today, your  
2 testimony is that \$152,000 for that time period doesn't  
3 look like that was the right amount?

4 A. Over the course of two -- over the  
5 course of two years.

6 Q. From March 1st of '08 through  
7 February 2nd of 2010.

8 A. No, this suggests that between -- that  
9 between -- right, March 1st of 2008 to March 1st, 2009  
10 they paid me \$81,000, no, no, not even -- not even --  
11 no.

12 Q. You dispute that amount?

13 MR. SNELL: He already told you.

14 THE WITNESS: Yes.

15 (Document marked for identification as  
16 Toggia Deposition Exhibit No. 15.)

17 BY MR. SCHNIEDERS:

18 Q. I'm going to mark as Exhibit 15 the next  
19 spreadsheet we had for this. I actually handwrote the  
20 Bates number on that one since they come from the Excel  
21 spreadsheet.

22 This one covers -- and it just had end dates on  
23 this spreadsheet, but the end dates are September 23rd  
24 of 2010 through November 5th of 2011, and that covers



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1     \$153,000. As you can see the requesters, the contract  
2     amounts are different than what you just saw, as are  
3     the dates. So is it your testimony -- that in 2010 and  
4     2011 that this \$153,000 is incorrect?

5                     MR. SNELL: Form, lacks foundation.

6                     Go ahead.

7                     THE WITNESS: I honestly don't recognize  
8                     any of this. I can tell you that often times  
9                     in the contract, there was a ceiling, so it  
10                    would say something like, in a given year, you  
11                    know, your compensation will not exceed, and so  
12                    these numbers like \$30,000, \$10,000, in my  
13                    mind, might have been a ceiling. I just, you  
14                    know, I mean, if you said to me, you know, in  
15                    your relationship with Ethicon between 1999 and  
16                    2011 was your total compensation the 153? I  
17                    mean, maybe. I mean, is this just accounting  
18                    on how they sort of -- but, yeah, I don't know.

19     BY MR. SCHNIEDERS:

20                    Q. That's fine. I just want to get your  
21     testimony on it. That's fine.

22                    MR. SNELL: You've already testified in  
23     the first deposition.

24                    THE WITNESS: Yes, I did. Okay. That's

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1 fine.

2 MR. SNELL: You don't have to accept it.

3 MR. SCHNIEDERS: Nobody is accepting. I  
4 said all I said we're doing is getting your  
5 testimony.

6 THE WITNESS: That's fine.

7 (Document marked for identification as  
8 Toggia Deposition Exhibit No. 16.)

9 BY MR. SCHNIEDERS:

10 Q. Exhibit 16 is Master Consulting  
11 Agreement. This one covers the time period that starts  
12 on February 1st of 2011 and ends on March 31st of 2012.  
13 It may have been a few years since you've looked at one  
14 of these doctor, but if you go back to Exhibit A,  
15 that's where it talks about what the fees are  
16 associated with it?

17 A. I'm sorry. Would you mind giving me a  
18 few more minutes to just --

19 Q. If you look at Exhibit A, there's boxes  
20 checked that cover this contract right here, and the  
21 first one is --

22 A. I apologize. I'm not with you. Can you  
23 tell me again where you are.

24 Q. Exhibit A.

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1           A.       Sure.

2           Q.       It's about three-fourths of the way  
3 through this, I would say. The bottom number on the  
4 Bates number ends with 167.

5           A.       Yes, okay. Sorry. Go ahead.

6           Q.       Under A it says, "Consultant agrees to  
7 perform the Services below for which the 'Yes' box is  
8 checked for the compensation set forth therein."  
9 Company-sponsored speaker programs is checked yes, and  
10 then if you read through there it says, "Consultant  
11 shall present scientific, clinical and related  
12 professional information by speaking at  
13 Company-sponsored seminars and meetings as requested by  
14 Company. Consultant shall disclose to attendees that  
15 he is being compensated by Company for the  
16 presentation. Consultant shall make such presentations  
17 on 8 occasions. The presentation will review stress  
18 urinary incontinence procedures. For each such  
19 speaking engagement, Company shall pay consultant  
20 \$3,000 per 8 hour day plus reasonable out-of-pocket  
21 expenses.

22                   And I'll tell you that eight times 3,000 is  
23 \$24,000. It says no under Subsection 2. It says no  
24 under Subsection 3. Under Subsection 4 it says

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1 "Preceptorship/Surgical Training, yes. Consultant  
2 shall allow visiting surgeons and visiting Company  
3 sales representatives to observe surgical procedures  
4 involving the practice of stress urinary incontinence,  
5 the clinical uses of stress urinary incontinence family  
6 of products and to consult with Consultant regarding  
7 such procedures applicable to patient confidentiality  
8 and consent requirements. In particular, Consultant  
9 agrees he or she shall secure appropriate patient  
10 consent to the presence of any third party during  
11 surgical training programs as necessary. Consultant  
12 shall allow such visits up to 9 occasions, and Company  
13 shall pay consultant \$3,000 for each such session per 8  
14 hour day."

15 And that adds up, if you take nine times 3,000,  
16 to 27,000.

17 If you go to the next page, it's checked no on  
18 Number 5, 6, 7. On 8 Other, it's checked as yes, and  
19 it says, Consultant shall perform other services  
20 designated below for, and it has a dollar sign and it  
21 says varies per hour, and the description of services  
22 is faculty training meetings and educational  
23 summits/forums. Negotiated rate to be no more than a  
24 maximum of \$375 rate/per hour.

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1           And then it goes down to say "B. The parties  
2   agree that compensation paid to consultant shall not  
3   exceed \$54,000 per contract term, except as may be  
4   mutually agreed in writing by the Parties."

5           Do you see that?

6           A.       Yes.

7           Q.       Do you recall this contract?

8           A.       Yes.

9           Q.       So with counsel's caveat that these --  
10   saying that these are agreed maximums, not payments  
11   that are made out, I'm keeping a running list of these  
12   amounts here.

13          A.       All right. Can I point out that the  
14   numbers you provided on this list for the period of  
15   time covered in this contract greatly exceed this  
16   \$54,000, which is one of the reasons why I don't  
17   believe that this represents actual compensation.

18          Q.       Sure, but you can also point out the  
19   fact that the dates and contracts often coincide at the  
20   same time because there's different consulting  
21   agreements that you signed at different times with  
22   different people, correct?

23                   MR. SNELL: Form, foundation.

24                   THE WITNESS: Can I disagree with you,

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1           because this document specifically refers to  
2           this as a Master Consulting Agreement, and  
3           everything on this list right here is  
4           designated under the Master Consulting  
5           Agreement. So these two documents don't agree.  
6           I mean, this is a completed document, and I  
7           have recollection. I have no idea where these  
8           numbers came from.

9   BY MR. SCHNIEDERS:

10           Q.       Fair to say that you don't believe in  
11           any given year you made over \$100,000 from Ethicon?

12           A.       I think \$31,000 was the highest I made,  
13           and I will tell you that that was when we were working  
14           on the PASS study. That had nothing to do with other  
15           stuff.

16                       (Document marked for identification as  
17           Toggia Deposition Exhibit No. 17.)

18   BY MR. SCHNIEDERS:

19           Q.       I'll keep going through and you can  
20           disagree with me on the numbers, that's fine, I'm just  
21           putting them on the record. This is 17.

22           A.       Fine.

23           Q.       And this is part of an e-mail that is  
24           titled Action Required with some numbers 2012 Master

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1 Consulting Agreement, Marc Toggia, MD, Incontinence  
2 Annual, and it's some other contract numbers there.

3 It says under here under line items, Number 1,  
4 Marc Toggia, MD, and then it says consulting fee. It's  
5 got a contract ID number, which if you want to  
6 reference it on the spreadsheet over there doesn't show  
7 up anywhere, and it's got an amount of \$14,250. I'm  
8 not asking if it's accurate. I'm asking if I read that  
9 correctly.

10 A. This is for 2012. I don't recall  
11 receiving -- I don't know that I received any  
12 compensation from them. I think this might be the  
13 amount that I was approved, the maximum amount. I have  
14 no idea. I have no idea what this refers to.

15 Q. And you see down at the bottom that the  
16 total cost of this contract is \$15,000.

17 Do you see that?

18 A. Yes.

19 Q. You can set that to the side. Give you  
20 what I'm marking as Exhibit 18, which is another  
21 consulting agreement.

22 (Document marked for identification as  
23 Toggia Deposition Exhibit No. 18.)

24 BY MR. SCHNIEDERS:

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1           Q.       This takes a slightly different form  
2     than the one we were looking at that was the master  
3     agreement, correct?

4           A.       Yes.

5           Q.       Although, if you go through, you'll see  
6     that when it gets to the third page, it starts to look  
7     a little bit more like the Master Consulting Agreements  
8     that we've seen before. On this one the agreement  
9     shall commence on April 1st, 2012 and then it goes  
10    through March 31st of 2013.

11           It is nearly identical in content. If you go  
12    to the page where you signed it, you signed it on  
13    February 6th of 2012.

14           Do you see that?

15           A.       Yes.

16           Q.       And Paul Parisi who is countersigned, do  
17    you know who Paul Parisi is?

18           A.       He is an individual that worked for  
19    Ethicon.

20           Q.       And on this one on the Exhibit A, it  
21    appears that there was a yes checked next to  
22    company-sponsored speaking program again, and it was  
23    for one occasion for \$3,000, and then the Number 4 the  
24    preceptorship/surgical training was checked as well,



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1 and that was for four occasions at \$3,000, and then  
2 moving to the end, everything else was checked no, and  
3 "The Parties agree that compensation paid to consultant  
4 shall not exceed \$15,000 per contract term, except as  
5 may be mutually agreed by the Parties."

6 Do you see that?

7 A. Yes.

8 Q. So I will tell you that I have gone to  
9 add up the amounts, and the amounts that I've added up  
10 from the spreadsheets and from these contracts we've  
11 been looking at after going through to make sure that  
12 the contract numbers didn't duplicate was \$389,000?

13 A. Sir, this was --

14 MR. SNELL: You got to let me object.

15 Objection, lacks foundation.

16 MR. SCHNIEDERS: Everybody has to let me  
17 ask my question first. That's how this works.

18 THE WITNESS: Fair enough.

19 BY MR. SCHNIEDERS:

20 Q. I have gone through and added up the  
21 amounts from the spreadsheets and from the contracts  
22 and made sure that they didn't duplicate any contract  
23 numbers, and it comes up to an amount of \$389,000. I  
24 think what you're going to tell me is that you were

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1 never paid \$389,000 from Ethicon?

2 MR. SNELL: My objection is lacks  
3 foundation, misstates the evidence.

4 THE WITNESS: What do you think that  
5 number represents? I don't understand. That  
6 was the maximum that I could have done. I can  
7 tell you, say specifically the first thing  
8 talked about giving presentations at a national  
9 meeting, or, you know, I can't -- other than --  
10 I can't tell you that I ever was asked to give  
11 that kind of a presentation. So even though it  
12 says I could have given that presentation,  
13 pretty much the only thing that I ever did in  
14 prof ed was teach cadaver labs, which maybe  
15 occurred once or twice a year, okay, or I  
16 precepted an individual, which, on average, may  
17 have occurred two to six times a year. That  
18 was probably -- you know, again, this might  
19 have been an allowance. You know, the company  
20 was approving a maximum amount. That does not  
21 reflect what I was paid by the company.

22 BY MR. SCHNIEDERS:

23 Q. I think you said, I just was looking at  
24 the record, you said that probably the most you ever

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1 got paid in any given year was 31,000?

2 A. My -- yes, my recollection from the  
3 earlier deposition, and, again, this may not be  
4 accurate, my recollection was that in 2011, I received  
5 \$31,000, and my recollection is that that related to  
6 the period of time that I was working on product  
7 development. It did not reflect preceptor time,  
8 lecturing time. That was never a big part of my role  
9 with the company.

10 Q. Okay. I'm going to mark as Exhibit 19  
11 this e-mail string.

12 (Document marked for identification as  
13 Toggia Deposition Exhibit No. 19.)

14 BY MR. SCHNIEDERS:

15 Q. We can certainly look at the top e-mail  
16 here in a moment, but it doesn't pertain to what we're  
17 here to talk about, but if you go down to the bottom,  
18 Ronald Horton writes an e-mail.

19 Do you know who Ronald Horton is?

20 A. No.

21 Q. But it says he's with ETHUS, which I  
22 believe is Ethicon US. He's written it to a Marti  
23 Heckman, Alyson Wess, Lissette Caro-Rosado, Paul Parisi  
24 and Matt Henderson.

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1 A. Right.

2 Q. Now, we've already talked about Paul  
3 Parisi.

4 Do you recognize any of those other names?

5 A. Vaguely.

6 Q. And the subject is KOL Usage, which, as  
7 we established before, is a term used in industry?

8 A. Yes.

9 Q. And it means most likely key opinion  
10 leader, and Ronald Horton writes, "All, please see the  
11 below list of highly used KOLs and the total pay they  
12 have received this year." This is written on Friday,  
13 November 19th, 2010?

14 A. Uh-huh.

15 Q. And if you look at the second page, it  
16 says Toggia total, \$153,000.

17 A. No.

18 Q. So someone at US group product director  
19 for uterine health, Ronald Horton believes that you  
20 were paid \$153,000 in 2010?

21 MR. SNELL: Object on the foundation,  
22 calls for speculation. Also, I think this  
23 e-mail was marked and covered in the earlier  
24 deposition, but go ahead, tell him what you

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1 think about that.

2 THE WITNESS: I'm sorry. Me tell him  
3 what I think about --

4 MR. SNELL: You can answer. I'm not  
5 sure if there's a question. The question was  
6 so someone at US group, product director Ronald  
7 believes you were pay \$153,000.

8 MR. SCHNIEDERS: In 2010.

9 MR. SNELL: In 2010.

10 THE WITNESS: I'm pretty confident that  
11 I didn't receive anything like that, sorry.

12 BY MR. SCHNIEDERS:

13 Q. So this e-mail is just wrong?

14 A. I don't know, sir. I was not part of  
15 this e-mail.

16 Q. Well, I understand that, Doctor. What  
17 I'm saying is it says that you were paid \$153,000 in  
18 2010. You're saying you weren't, so it's wrong, right?

19 MR. SNELL: Lacks foundation.

20 THE WITNESS: Yes, I'm telling you that  
21 I did not receive that compensation.

22 BY MR. SCHNIEDERS:

23 Q. Does that mean that your group received  
24 that compensation?

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1 A. No.

2 Q. Did anyone on your behalf receive that  
3 compensation?

4 A. No, not to my knowledge.

5 MR. SCHNIEDERS: Marking as Exhibit 20  
6 this e-mail string.

7 (Document marked for identification as  
8 Toggia Deposition Exhibit No. 20.)

9 BY MR. SCHNIEDERS:

10 Q. I'll let you familiarize yourself with  
11 it, the e-mail from Joy de los Reyes on down is the one  
12 I'm talking about. The very bottom one is an e-mail  
13 from you.

14 So, Doctor, this is an e-mail that you wrote  
15 from your e-mail address that we will make sure doesn't  
16 show up anywhere it's not supposed to, to Melissa  
17 Chaves.

18 Are you familiar with Melissa Chaves?

19 A. I recognize the name. I honestly  
20 can't -- I don't know what role she plays in the  
21 company.

22 Q. The subject is "thanks," and it says,  
23 Melissa, I wanted to thank you again for including me  
24 on the sling discussion panel yesterday. I very much

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1     enjoy working on these types of panels and did  
2     appreciate what the others had to say on the other  
3     approaches. It's fascinating how different approaches  
4     work equally well in different hands. Thought it went  
5     very well, and I received a lot of positive feedback  
6     afterwards from the audience. I think that everyone  
7     felt that it was fairly balanced, and several folks  
8     mentioned that they were glad to see that Ethicon is  
9     still very much supportive of the retropubic design, as  
10    many feel it is still your best product.

11           That said, it has occurred to me that your  
12    company spends virtually no time on TVT-R training, and  
13    this is something you may want to consider revisiting,  
14    especially as you look to bring surgeons back to the  
15    TVT family of products.

16           Now, when you said "bring surgeons back to the  
17    TVT family of products," what did you mean?

18           A.     Okay. So my recollection of the  
19    contents of this discussion is that Ethicon held a  
20    meeting of faculty members. As part of that meeting,  
21    they asked three of us to volunteer to do a  
22    debate-style discussion. I represented the retropubic  
23    approach. Another doctor represented the obturator  
24    approach. The third doctor represented the TVT Secur

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1 approach. They then presented us with a patient case  
2 and then asked us to defend why we would choose  
3 whatever approach we were assigned to. My recollection  
4 is that I was assigned to the retropubic approach. It  
5 was kind of a debate style amongst colleagues.  
6 Everybody I thought did a very good job of defending  
7 the position that they were asked to represent.

8           Again, it was a -- it was a debate so we were  
9 just asked to defend our position, and at the end of  
10 that debate, people commented to me that they thought  
11 that my argument for that particular case for the  
12 debate was very convincing. As you well know, the  
13 majority of what I do in my clinical practice is the  
14 TVT retropubic approach. As my expert report  
15 previously illustrated, I believe that that is the  
16 product that has the most data of any procedure for  
17 incontinence in our history and that that represents  
18 very solid data, and so obviously I feel very strongly  
19 that that is the procedure of choice. That's my  
20 opinion.

21           So I was commenting to them that, you know, my  
22 opinion was that they should spend more time, you know,  
23 training and talking about this thing, and I just  
24 simply told them that I would be happy to participate



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1 in further -- they wanted to invite me to give a  
2 further debate or another talk in front of my  
3 colleagues that I enjoyed participating in that type of  
4 activity.

5 Q. So you wrote this in order to help  
6 Ethicon bring surgeons back to the TVT family of  
7 products, right?

8 MR. SNELL: Objection, misstates.

9 THE WITNESS: No, no. I just -- you  
10 know, I just thanked them. I was not paid  
11 separately to participate in the debate. I was  
12 just thanking them for thinking of me as a --  
13 as somebody who could speak in a debate fashion  
14 on this topic. And, again, my feeling was is  
15 that the TVT sling had the most data out there  
16 relative to other retropubic products, and I  
17 felt quite confident that this was the product  
18 that was -- according to the data, had the most  
19 efficacy and safety and just, you know, the  
20 amount of data presented and that I thought  
21 that they -- if they focused on presenting that  
22 data the way that I did in the debate, that  
23 hopefully others would also see that the TVT is  
24 the best procedure based upon sound science for

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1           the treatment of stress incontinence across the  
2           entire spectrum of the disease, mixed  
3           incontinence, plain stress incontinence, repeat  
4           surgery, et cetera.

5           Q.       And you wrote here, "Certainly, users of  
6           other retropubic products could be persuaded, and  
7           perhaps those using obturator approaches could be asked  
8           if they would like to add the retropubic approach for  
9           their more complicated patients, (eg expand upon their  
10          skill set, now that they are comfortable with TOT.)  
11          From there, it might be easier to re-explore the  
12          possibility of them using your brand of obturator  
13          sling."

14                 So it's a sales pitch, right?

15                         MR. SNELL:   Objection.

16                         THE WITNESS:   I was speaking to a  
17                         salesperson.   I again was trying to use  
18                         language.   I don't sell anything myself.   I  
19                         have no vested interest in what they get  
20                         revenue wise.   I certainly don't see any of it.  
21                         I was just defending TVT retropubic as the gold  
22                         standard in our field and just wanted to let  
23                         them know that I thought that that was -- you  
24                         know, in my opinion, as a minor player, you

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1 know, in this world for them, that this is  
2 where I thought I was most passionate about,  
3 and, again, I was speaking to the data and the  
4 science, that to me this was a no brainer. You  
5 know, you should try to reengage people based  
6 on the science and the data.

7 Q. And you offered to do a dinner talk on  
8 the merits, correct?

9 A. Yes. That might have been with other  
10 members of her team. I don't know.

11 Q. Sure. But you're compensated for dinner  
12 talks as a teacher, correct?

13 A. If I was speaking to -- I mean, I was  
14 not -- like I said, I was not compensated for this  
15 participation. If I had dinner with them locally, I  
16 don't get paid for that kind of stuff. Again, I'm just  
17 an advocate for the TVT retropubic approach. I thought  
18 that I made a strong argument why the data supports the  
19 retropubic approach as the best procedure. I got a lot  
20 of positive feedback that my analysis was very  
21 convincing, and given that that's one of my strengths,  
22 the ability to read the data as I presented here  
23 independently and articulate a comparison, I was simply  
24 offering that, and that's all I remember.

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1 Q. Okay.

2 MR. SCHNIEDERS: I'll object and move to  
3 strike that last answer as nonresponsive, and,  
4 Doctor, if we don't keep it down to -- because  
5 I'm running out of time but...

6 THE WITNESS: I'm sorry that you don't  
7 like my answer, but that's my answer.

8 BY MR. SCHNIEDERS:

9 Q. I asked you if you were compensated for  
10 dinner meetings. I don't think that was responsive.

11 A. I don't think I've ever been  
12 compensated. I don't think I've ever been compensated  
13 for a dinner meeting. I don't think I've ever been  
14 invited to participate in a dinner meeting.

15 (Document marked for identification as  
16 Toggia Deposition Exhibit No. 21.)

17 BY MR. SCHNIEDERS:

18 Q. This is Exhibit 21.

19 MR. SNELL: I'm reading the transcript  
20 where he does say.

21 BY MR. SCHNIEDERS:

22 Q. So, anyway, this is Exhibit 22, and this  
23 is another e-mail chain and, again, if you look at the  
24 very top, it's got Ronald Horton on it again, who we

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1 just saw on that other e-mail regarding the top used  
2 KOLs, but down below that, there's an e-mail from a  
3 gentleman named Scott Jones.

4 Do you know Scott Jones?

5 A. Yes.

6 MR. SNELL: Counsel, I think you  
7 identified this as Exhibit 22, but I think it's  
8 21, just so we get a clear record. You started  
9 off on 21 and then you said 22.

10 MR. SCHNIEDERS: It's 21.

11 BY MR. SCHNIEDERS:

12 Q. So under here it says there's a heading  
13 that says "Convention Updates," and then it says, "AUGS  
14 was another huge success."

15 Does AUGS have a convention every year?

16 A. No. AUGS has an annual scientific  
17 meeting.

18 Q. Okay.

19 A. Understand that industry looks at these  
20 things different than how we look at it.

21 Q. I can believe that.

22 A. Right.

23 Q. "The day prior to the official meeting  
24 start, we hosted 2 educational events for urogyn

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1 fellows. These events are part of our fellowship  
2 education strategy being led by Jen Paradise, and  
3 fellow directors are taking of EWHU's involvement."  
4 And then the second bullet point or a line point there  
5 says, "The Prosima & TVT Exact symposium was well  
6 attended and highlights another success led by  
7 Dr. Toggia & Dr. Garriis."

8 Do you remember presenting at the Prosima and  
9 TVT Exact symposium at AUGS in 2010?

10 A. I would have presented the TVT Exact  
11 module of that. I would not have presented the  
12 Prosima.

13 Q. And you would have been there on behalf  
14 of Ethicon, correct?

15 A. Typically, if I'm remembering the event,  
16 I think this was a industry sponsored lunch, and during  
17 the lunch hour, they provided lunch for whatever it is,  
18 20 or 30 participants, and I would have given, you  
19 know -- as you know, I was involved in the development  
20 of TVT Exact, and so I would have provided some kind of  
21 an update, you know, or some kind of just general  
22 educational talk, as we've provided here.

23 Q. And you would have been compensated for  
24 that, correct?

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1 A. Yes, I would have thought so.

2 Q. And this was in 2010, which was the year  
3 that we saw the e-mail where they say you were paid  
4 \$153,000, correct?

5 MR. SNELL: Foundation.

6 THE WITNESS: I will -- what's the date  
7 here? I would say the event occurred in 2010.

8 (Document marked for identification as  
9 Toggia Deposition Exhibit No. 22.)

10 BY MR. SCHNIEDERS:

11 Q. I'm going to hand you what I'm marking  
12 as Exhibit 22. This is an e-mail from a gentleman  
13 named Kevin Frost.

14 Do you know Kevin Frost?

15 A. I do not.

16 Q. The subject is "2011 Incontinence &  
17 Pelvic Floor Recap," and then it begins, "Hello all,  
18 the 2011 Ethicon Women's Health & Urology Incontinence  
19 and Pelvic Floor Summit was recently held in Sonoma,  
20 California (March 31-August 2nd)."

21 Are you familiar with the incontinence and  
22 pelvic floor summit that Ethicon would hold annually?

23 A. Yes.

24 Q. And was it typically in Sonoma, or did

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1 it move around?

2 A. No. I only attended a handful of them.  
3 This was the only one that I had -- I don't know if  
4 they had ever been there before. I had only been to  
5 one that was in Sonoma.

6 Q. Just so we're clear on the record here,  
7 if you go back to exhibit -- it's the e-mail that's  
8 talking about training around the TVR. You see this  
9 one, Doctor, Bates ends with 3824.

10 What exhibit is that, Doctor?

11 A. Exhibit 20 is an e-mail from 2009.

12 Q. Okay. So in Exhibit 20, if you'll see  
13 there it says under the subject "RE: thanks TVTR Prof  
14 Ed training/summit comments."

15 Is it possible that when you met Ms. Chaves  
16 that that was at the summit?

17 A. Excuse me?

18 Q. Is it possible that when you met  
19 Ms. Chaves and then wrote this e-mail that was just  
20 after the summit?

21 A. I'm sorry. I thought the summit was  
22 2011. This is 2009.

23 Q. The summit was every year from my  
24 understanding, and you said that you only went to it



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1     periodically, so I'm showing you from 2009, you go down  
2     here where it says Dr. Toggia regarding a TVT panel at  
3     the summit?

4             A.       Oh, okay. I see. I'm sorry. Yes.

5             Q.       And that's in February of 2009?

6             A.       Yes.

7             Q.       So you would have been there in February  
8     of 2009, and then looking at the document we're looking  
9     at now, this is 2011, correct?

10            A.       Yes.

11            Q.       And if you go down it says in the middle  
12    there a breakdown of this year's attendees are as  
13    follows, 31 gyny, 31 urogyny (including 4 fellows), 19  
14    urologists. And then at the very bottom, it says, "a  
15    special thanks to the following customers who served as  
16    meeting moderators," and it lists you along with three  
17    other doctors.

18            Do you see that?

19            A.       Yes. I'm sorry, there are three more  
20    names on the other page. I understand your point.

21            Q.       There are three on this page, and then  
22    there's three additional on the other page?

23            A.       Three others besides myself, yes.

24            Q.       And it refers to you as a customer. Do

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1 you know why the company would refer to you as a  
2 customer?

3 A. I don't, because I use their products,  
4 perhaps.

5 Q. At the end of the day they're selling  
6 doctors on using the products, not the patient, right?

7 MR. SNELL: Form, foundation.

8 MR. SCHNIEDERS: I'll withdraw.

9 BY MR. SCHNIEDERS:

10 Q. You see where it says customers, and  
11 it's referring to you and some other of your  
12 colleagues, correct?

13 A. Yes. I don't know, but I don't  
14 understand why I'm referred to as a customer.

15 Q. Okay. Set that to the side.

16 MR. SCHNIEDERS: I'm going to mark this  
17 Exhibit as 23.

18 (Document marked for identification as  
19 Toggia Deposition Exhibit No. 23.)

20 BY MR. SCHNIEDERS:

21 Q. This will be a very brief question,  
22 Doctor, and I just want to call your attention to it.  
23 It says under the subject, "Let me know your  
24 thoughts... this is a draft." So this e-mail that

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1 we're looking at right here, the second doesn't show  
2 that it went to you, but the bottom one down here, the  
3 draft itself was a draft of an e-mail to you.

4 Do you see that?

5 A. Okay.

6 Q. And it's from a woman named Rhonda  
7 Peebles.

8 Do you know Rhonda Peebles?

9 A. Yes.

10 Q. In that she says, "I am excited to  
11 announce that Ethicon Women's Health & Urology received  
12 approval for a new TVT sling, Gynecare TVT Exact, and  
13 will be launching very quickly. We are putting  
14 together 2 key customer events to introduce the product  
15 and would love for you to be a part of the launch. You  
16 were one of the initial physicians to be exposed to the  
17 product via our customer labs last fall so your input  
18 would be invaluable."

19 Do you recall if you attended that event?

20 A. I don't even know that I ever received  
21 this e-mail. I don't think I attended either of those.  
22 I don't recall.

23 Q. Okay. That's fair. Set it aside.

24 Now, would you consider yourself when you're

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1 working on behalf of Ethicon, not for Ethicon, but on  
2 behalf of Ethicon or any other device company to be a  
3 salesperson for them?

4 A. Not at all.

5 Q. Okay. Are you an advocate for them?

6 A. I'm an advocate for women's health. I'm  
7 an advocate for women that suffer with pelvic floor  
8 disorders, and I'm for anything that I can do that  
9 helps to increase the awareness of these conditions and  
10 treatments for it. As you know, this is a major public  
11 health burden, and there are more women that suffer  
12 from incontinence and prolapse than we currently have  
13 manpower to care for.

14 Q. Earlier when you were talking about the  
15 TVT-R panel that you had been part of, you said you  
16 were advocating for that approach because you believe  
17 that's the best approach, right?

18 A. Understand, I was assigned it, right.  
19 So if I had been assigned obturator, my assignment was  
20 the same and I would have presented my argument in that  
21 regard. That said, I'm sure that they chose me for  
22 TVT-R because they knew that despite the fact that  
23 other products had been developed, despite the fact  
24 that I had participated in trials with TVT Secur and

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1     that I taught all three products, that my personal  
2     practice was still very much aligned with the  
3     retropubic approach, right.

4             Q.       And, similarly, your belief in the TVT  
5     product has made you an advocate for it because you  
6     believe it's the safest option, right?

7             A.       Well, I believe that the experience and  
8     the publications support the safety and the  
9     effectiveness of that product and that it is the most  
10    vigorous scientific data that we have for any product  
11    in the history of incontinence treatment.

12            Q.       But -- and you've advocated for that  
13    product and other products you believe in to fellow  
14    surgeons when they were talking about it, right?

15                   MR. SNELL:   Form.

16                   THE WITNESS:   Specifically that product,  
17                   yes.

18    BY MR. SCHNIEDERS:

19            Q.       But you would never consider anything  
20    that you've done to be advertising for Ethicon, right?

21            A.       No.

22                   MR. SCHNIEDERS:   Off the record.

23                               (Brief recess taken at 5:59 p.m.)

24                               (Deposition resumes at 6:02 p.m.)

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1 BY MR. SCHNIEDERS:

2 Q. We're back on the record after a short  
3 break. Doctor, I'm going to mark as Exhibit 24 an  
4 e-mail chain.

5 (Document marked for identification as  
6 Toggia Deposition Exhibit No. 24.)

7 BY MR. SCHNIEDERS:

8 Q. And this is from, again, Rhonda Peebles,  
9 who we just saw an e-mail from her a moment ago, right?

10 A. Yes. I'm sorry, just reviewing this.

11 Q. And it's to a Lindsay Froelich.

12 Do you know her?

13 A. Do not, no.

14 Q. All right. It starts off, "Sorry for  
15 the delay. I've been swamped with launch meeting  
16 planning. Feel free to put time on my calendar the  
17 week of the 17th to discuss further, Rhonda."

18 And this is in response, if you go to the  
19 second page, to questions that Ms. Froelich was asking  
20 with regard to TVT Exact.

21 And so she answers several. Under Number 3, a  
22 question she's asked is "Is there any clinical data  
23 that will be published or presented this year?" And  
24 Rhonda Peebles writes back, "There is no specific

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1 clinical data. Exact will leverage data from TVT  
2 classic."

3 Is that an accurate statement, to your mind?

4 MR. SNELL: Foundation, speculation.

5 THE WITNESS: I'm sorry, I don't -- I  
6 don't see it. Is there two pages?

7 BY MR. SCHNIEDERS:

8 Q. There are two pages.

9 A. Okay.

10 Q. But it's the front page you need look  
11 at. You don't need to go back and forth with the  
12 questions. They're written above each spot. So go to  
13 the first page.

14 A. Oh, I'm sorry.

15 Q. That's okay. If you go to question 3,  
16 you will see the question and the answer.

17 A. Okay. Sure. What's your question?

18 Q. So the question written there "Is there  
19 any clinical data that will be published or presented  
20 this year? Answer, there is no specific clinical data.  
21 Exact will leverage data from TVT classic."

22 Do you believe that statement to be true?

23 A. I'm not aware whether data was -- I'm  
24 not aware of data being presented that year.

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1 Q. Okay. When she says "Exact will  
2 leverage data from TVT classic," what does that mean to  
3 you?

4 MR. SNELL: Objection to form.

5 THE WITNESS: How would I know what  
6 Ms. Peebles was meaning? I mean, the product  
7 is the same. The mesh itself is the same. The  
8 modifications that we made to the product is we  
9 changed the handle design. We made the trocar  
10 thinner. We made the handle disposable. Other  
11 than that, there really is no difference. It's  
12 sort of -- was sort of a refresh of the  
13 product.

14 BY MR. SCHNIEDERS:

15 Q. Under question 5, What do you hope to  
16 achieve through PR with this program? Answer,  
17 increased awareness during the launch phase.

18 6. What are the important  
19 magazines/newsletters you would like to see cover this  
20 product? Answer, Urology and OB-GYN throw-away  
21 journals.

22 7. There are major medical meetings -- strike  
23 that. 7. Are there major medical meetings where you  
24 will be unveiling/displaying this product? And it



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1 lists AUA, AUGS and ICS-IUGA, the advocacy groups,  
2 correct?

3 A. Yes.

4 Q. And then are any important advocacy  
5 groups you'd like to reach at launch? Do you have any  
6 relationships with them already? Good question, we  
7 should discuss.

8 And lastly on 9, who do you recommend as  
9 internal and external (KOLs) spokespeople for media  
10 interviews? Internal, Dr. Aaron Kirkemo.

11 Do you know Aaron Kirkemo?

12 A. Dr. Kirkemo was a -- one of the medical  
13 directors for Ethicon women's health at the time.

14 Q. Okay. And then Howard Goldman, the  
15 urologist from Cleveland Clinic that we discussed  
16 earlier --

17 A. Yes.

18 Q. -- that is also one of the authors on  
19 the AUGS mesh position statement?

20 MR. SNELL: Form.

21 THE WITNESS: Yes.

22 BY MR. SCHNIEDERS:

23 Q. And it says, "although the CC may not  
24 allow doctors to participate in PR."

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1 A. Yes.

2 Q. And then lastly it mentions Dr. Marc  
3 Toggia, urogyn, Philadelphia.

4 You see that?

5 A. Yeah.

6 Q. Do you recall being approached by Ms.  
7 Peebles to be a spokesperson for TVT Exact?

8 A. Yes, I recall that I was asked to help  
9 with an article that addressed urinary incontinence in  
10 women, treatment options in women, yes. You understand  
11 that, again, I was fairly involved in the development  
12 of the TVT Exact product and served as -- I think the  
13 video on the surgical steps is myself, you know,  
14 demonstrating the procedure, so yes.

15 MR. SCHNIEDERS: I'm going to mark as  
16 Exhibit 25.

17 (Document marked for identification as  
18 Toggia Deposition Exhibit No. 25.)

19 BY MR. SCHNIEDERS:

20 Q. This document that is titled "TVT Exact:  
21 Editor's Backgrounder (Gynecology).

22 A. Mm-hmm.

23 Q. If you look, do you know what a  
24 backgrounder is, Doctor?

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1 A. I do not.

2 Q. Are you familiar with the publication  
3 Gynecology?

4 A. No. I don't think that that was the  
5 publication. I think it's the subject.

6 Q. Do you recall what publication this  
7 appeared in?

8 A. Cosmopolitan, Red Book, I think it was a  
9 consumer magazine, Reader's Digest. I honestly -- I  
10 vaguely recall that it was a direct-to-consumer thing.

11 Q. And do you recall that you were the  
12 spokesperson within it?

13 A. I don't think that I would say that I  
14 was a spokesperson. I think that I contributed some  
15 quotes.

16 Q. I think it starts off the title is  
17 "Gynecare TVT Exact: Building on the Legacy of  
18 Gynecare TVT," and it says, according to Marc Toggia,  
19 MD, chief of urogynecology for the Main Line Health  
20 System in suburban Philadelphia, gynecologic surgeons  
21 now have a new option when retropubic placement of a  
22 midurethral sling is the treatment of choice in women  
23 with stress urinary incontinence. Gynecare TVT Exact.  
24 You see that?

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1 A. Mm-hmm.

2 Q. It goes on, "Gynecare TVT Exact retains  
3 cardinal features of the Gynecare TVT retropubic  
4 system, including the laser-cut mesh, protective  
5 sheath, trocar geometry, and rigid needle design of the  
6 original Gynecare TVT. TVT Exact is engineered with  
7 enhancements designed to further reduce tissue and  
8 organ damage."

9 Now, the portion that was already written for  
10 you, did you write that?

11 A. I don't believe so.

12 MR. SNELL: Form.

13 BY MR. SCHNIEDERS:

14 Q. Going on to the next page, about two  
15 lines down, I guess on Line 3 it says -- is the next  
16 part that I see that you appear in the article, Doctor.  
17 It says, Dr. Toggia noted that a good outcome of  
18 minimally invasive surgery to place suburethral sling,  
19 whether through the retropubic, transobturator, and I'm  
20 not even going to get that one. I'll let you read  
21 this. Why don't you read this.

22 A. Well, it's obturator. It's spelled  
23 wrong or ischioirectal space, begins with the surgeon's  
24 precision and control.

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1 Q. And did you write the passage that your  
2 -- this quote from you right here?

3 A. I don't know. It just says that  
4 Dr. Toggia noted, so I may have had a discussion and an  
5 interview, and they may have paraphrased me. I  
6 honestly don't know.

7 Q. If you go to the next page at the top,  
8 Line 1 it says, "Dr. Toggia observed that there has  
9 been a great deal of concern about synthetic meshes.  
10 And there's good reason for physicians and patients to  
11 exercise due diligence when considering a suburethral  
12 sling to treat SUI."

13 Do you agree with that statement?

14 A. I was referencing the FDA safety warning  
15 at the time.

16 Q. And, to be fair, that was the FDA safety  
17 warning of 2008, correct?

18 A. I believe so, yes.

19 Q. So the FDA safety warning of 2011 hadn't  
20 come out at that point, right?

21 A. Sure. I mean, to be fair, I don't see a  
22 date, but, you know, I will assume, let's say, for  
23 argument sake that this was in the same time frame as  
24 when the product was being launched. That would be my

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1 assumption.

2 Q. I can show you a little bit more  
3 specifically.

4 A. I think we're saying the same thing.

5 Q. I agree.

6 A. I don't want to waste anybody's time.

7 (Document marked for identification as  
8 Toggia Deposition Exhibit No. 26.)

9 BY MR. SCHNIEDERS:

10 Q. Marking this as Exhibit 26. Doctor,  
11 this is another e-mail from Ms. Peebles. I'm sorry.  
12 The top of it is an e-mail from Ms. Peebles to someone  
13 at a group called idanda.com, something like that, and  
14 it says "OB-GYN backgrounder...I'll give you a call,"  
15 and then underneath it is an e-mail from you to  
16 Ms. Peebles.

17 A. Okay.

18 Q. And it looks like it says, "Rhonda, here  
19 you go," and it appears that at least part of the quote  
20 that we just saw in that backgrounder is written right  
21 there.

22 Do you recall if you typed up -- do you recall  
23 typing up an e-mail and sending it to Rhonda to give  
24 her a quote?

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1           A.       I don't recall it, but I think it speaks  
2     for itself and, certainly, you know, I'm sort of  
3     reading through this, and I'm saying to myself, I never  
4     would have said ischioirectal, we don't use that  
5     passage, and I obviously read this for factual accuracy  
6     and I was responding to her and making suggestions.

7           Q.       And did you notice what you called the  
8     subject there when you sent it back to her?

9           A.       TVT ad.

10          Q.       TVT ad?

11          A.       TVT ad.

12          Q.       Is that an advertisement for TVT?

13          A.       I was probably whatever they were --  
14     whatever they were referencing it to me.

15          Q.       Well, I don't -- to be fair, and this is  
16     how they produced it to us, and we all know how e-mail  
17     works, it usually says re: or forward or something  
18     before that if you're just replying. That looks like a  
19     subject you picked out?

20                 MR. SNELL: Objection, foundation.

21                 THE WITNESS: Okay. Again, my  
22     recollection was there was a short article in  
23     some consumer journal. It might have been  
24     Reader's Digest. It might have been

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1           Cosmopolitan, you know. I was glad to see them  
2           being raising awareness directly to women, you  
3           know, telling them that there were treatment  
4           options for stress incontinence.

5       BY MR. SCHNIEDERS:

6           Q.       To be fair, they were only talking about  
7           their product, right?

8           A.       I don't know. I mean, I don't know the  
9           content of the entire article, but I would not -- I  
10          would suspect that they would just talk about theirs.  
11          I don't know what the rest of the article entailed.

12          Q.       It's an ad for TVT?

13          A.       I don't know that it's an ad for TVT. I  
14          just referred to it as TVT ad. I don't know why I  
15          referred to it as TVT ad.

16                   (Document marked for identification as  
17           Toggia Deposition Exhibit No. 27.)

18       BY MR. SCHNIEDERS:

19          Q.       I'm going to mark as Exhibit 27 a  
20          spreadsheet that was given to us. Don't worry about  
21          the front page. It's extremely hard to read, but we're  
22          not going there. It's going to be several pages in.

23          A.       Okay.

24          Q.       So the first page at the top lots like



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1 it says Gynecare Interceed, and obviously it's talking  
2 about the barrier product, and then it goes forth, and  
3 each page has a different product on it. The product  
4 that I want to call attention to is on Page 9631 are  
5 the last four numbers of the Bates. It's not perfect,  
6 but it's better to read than the other pages.

7 A. Okay.

8 Q. At the top you see it says "Gynecare TVT  
9 Exact Tension-free Support for Incontinence Roadmap"?

10 A. Uh-huh.

11 Q. And then it's got several different  
12 categories on the left-hand side that say Strategy,  
13 Sales Targeting, Launches, Marketing Tools, Key  
14 Messages, Awareness, Contracting/Promotions and Prof Ed  
15 Support.

16 Under "Launches" it says Gynecare TVT Exact,  
17 Gynecare TVT Abbrevio launched May 2010 and  
18 February 2011 respectively.

19 You see that?

20 A. Mm-hmm.

21 Q. And then under "Marketing Tools" it says  
22 Gynecare TVT Exact, and it lists marketing tools on the  
23 right-hand side, Gynecare TVT Exact sales aid, Gynecare  
24 TVT Exact slim jim, Gynecare TVT Exact procedural

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1 video, Gynecare TVT Exact procedure steps flash card.  
2 And then the female patient article featuring  
3 Dr. Toggia is listed as a marketing tool.

4 If you go down to "Awareness," you see that  
5 scientific meeting presence, and there's several  
6 different advocacy groups that are all going to be  
7 presented to, including AUGS, correct?

8 MR. SNELL: Objection, foundation,  
9 advocacy groups.

10 THE WITNESS: Yeah, I wouldn't use the  
11 word advocacy groups. These are professional  
12 organizations, but I see what they're saying.  
13 I don't have any involvement in that.

14 (Document marked for identification as  
15 Toggia Deposition Exhibit No. 28.)

16 BY MR. SCHNIEDERS:

17 Q. I've marked as Exhibit 28 this document,  
18 it's titled "Overview," and it's got a paragraph at the  
19 top that says on January 30th, 2012 an approved  
20 communication (VP of sales & marketing, RBDs, director  
21 of communication GPD, PD were briefed on this  
22 communication) went out to approximately 300 surgeons  
23 who specialize in pelvic surgery (many of whom are  
24 faculty for EWHU) notifying them of the following.

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1 Bullet point reads, in 2012, we will continue to  
2 facilitate these types of important discussions in a  
3 variety of formats but will not be holding a one-time,  
4 formal summit meeting. Instead, we plan to utilize  
5 other interactive mediums and venues that will allow  
6 for more frequent and meaningful dialogue with you and  
7 your colleagues.

8 There was a very loud and emotional response to  
9 this notification, which has provided the EWHU  
10 organization the opportunity to re-evaluate how we will  
11 need to communicate with this group regarding the FAD  
12 mesh situation.

13 See what you've just read there?

14 A. Yes.

15 Q. Do you know what the FAD mesh situation  
16 is?

17 A. No.

18 Q. Okay. This is January 30th of 2012 is  
19 what it says, and that's just after the FDA had  
20 released their bulletin in 2011, correct?

21 A. Mm-hmm.

22 Q. Sorry. I messed up the question, and  
23 then you said uh-huh. Was that correct?

24 A. I'm sorry, that is correct. I mean, I

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1     assume   that's yes.

2             Q.       So it's reasonable to say, although we  
3     don't know sitting here, but that probably means the  
4     FDA mesh situation, because I don't know what FAD  
5     means?

6             A.       I don't know that, sir. I don't know  
7     that. I can't speak to that.

8             Q.       I appreciate that, but we do know that  
9     this is, from a temporal standpoint, just after the FDA  
10    released its bulletin, correct?

11            MR. SNELL:   Form.

12            THE WITNESS: I don't know. All I know  
13            is this communicates that a discussion that  
14            they were considering not holding another  
15            summit.

16    BY MR. SCHNIEDERS:

17            Q.       And in 2011 the FDA's release is  
18     ultimately what precipitated several products being  
19     pulled from the market by Ethicon, correct?

20            MR. SNELL:   Lacks foundation.

21            THE WITNESS: I don't know the  
22            relationship between the two, in all honesty.  
23            I was not part of that decision.

24    BY MR. SCHNIEDERS:

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1 Q. And you haven't been provided any  
2 documents on that either?

3 MR. SNELL: Objection, misstates earlier  
4 testimony.

5 THE WITNESS: I don't have an answer for  
6 your question.

7 BY MR. SCHNIEDERS:

8 Q. So if you go down it says, "Key  
9 Takeaways," and it's in bold face-to-face "meetings are  
10 being requested by the majority of respondents. They  
11 want a forum to vent, share & brainstorm on the future.  
12 Lack of understanding on the current situation & EWHU's  
13 position needs to be clarified."

14 Third bullet point, "A feeling that the company  
15 is supporting them needs to be delivered. Interactive  
16 meetings have a role but second to face-to-face."

17 Do you recall receiving a communication that  
18 would have told you that they were not going to have a  
19 summit in 2012?

20 A. Vaguely.

21 Q. If you go to the second page, there's a  
22 title that says "Feedback from Surgeons."

23 A. Okay.

24 Q. And then there are numbers and the first

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1 one is Bob Shull.

2 Do you know Bob Shull?

3 A. I do, yes.

4 Q. Second one is Doug Grier.

5 Do you know Doug Grier?

6 A. I do not, no.

7 Q. And Mike Vardy, then Neena Agarwala and

8 then there you are, Doctor, Marc R. Toggia, M.D.,

9 Number 5.

10 Do you see that?

11 A. Yes.

12 Q. And what you've written here is, "Given

13 the current controversies and challenges that we

14 physician are facing with regards to the use of vaginal

15 mesh, I would like to argue that we need this type of

16 meeting now more than ever. The future for vaginal

17 mesh seems somewhat uncertain, however, many of us

18 still believe that it serves a vital, albeit more

19 limited role."

20 Continues on, "Ethicon's role in providing

21 peer-to-peer support with regards to new and innovative

22 products is what has separated your company from the

23 rest of the field. Ethicon's willingness to partner

24 with and support surgeons in this regard has been

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1 second to none.

2 I would ask you to reconsider this decision.

3 If cost and travel are a major deterrent, I might  
4 suggest that you consider a lower cost venue, such as  
5 Philadelphia, or returning to Florida. I am sure that  
6 many of us would be willing to sacrifice the bells and  
7 whistles to simply get together and meet again."

8 Did I read that correctly?

9 A. Yes.

10 Q. Going back to the first page statement,  
11 you wrote, "The future for vaginal mesh seems somewhat  
12 uncertain, however, many of us still believe that it  
13 serves a vital, albeit more limited role."

14 What did you mean by "a vital, albeit more  
15 limited role"?

16 A. Well, you know, obviously the FDA's  
17 statement was going to be interpreted differently by  
18 many people, including people of your profession, sir,  
19 and obviously this was going to create challenges  
20 really in how we speak to people, you know, patients,  
21 women, women that had it implanted previously, people  
22 that were currently planning on implanting it.

23 At the time I don't believe that I was aware of  
24 any plans to pull the product. The FDA warning --

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1    yeah, the FDA warning also -- I mean, most of us  
2    involved at this level were not aware of the numbers of  
3    complications that had been reported to the FDA. I  
4    think we were surprised because, according to the  
5    literature that we were reading and our own experience,  
6    we were not seeing that complications but also the FDA  
7    was not very clear. The distinction -- their initial  
8    statement seemed to sort of blend stress incontinence  
9    with prolapse repair, whereas many of us thought that  
10   they were referring specifically to prolapse repair.

11           And so in the past, the summit meeting was an  
12   opportunity to bring people together and foster  
13   discussions, and I was pointing out to them that, you  
14   know, in that regard, it was still very variable to  
15   bring us all together so that we could discuss, you  
16   know, how are we going to counsel patients moving  
17   forward, how do we counsel patients that have been  
18   implanted and are doing well but have concerns. You  
19   know, immediately people were saying that there was a  
20   recall, when, in fact, there wasn't a recall.

21           Again, most of us were reading the literature,  
22   literature supported that this was a safe procedure  
23   with excellent safety and efficacy. Our own experience  
24   would support that, mirror that as well. So it seemed



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1 a little bit out of sync.

2 And, you know, again, Ethicon is based in New  
3 Brunswick, New Jersey, which is a stone's throw from  
4 Philadelphia. I was just saying to them, look, let's  
5 still have this meeting, it could be a quick meeting.  
6 You know, let's just get the usual group together,  
7 wherever it might be convenient. Again, most of the  
8 users, my understanding, were East Coast users. That's  
9 why I said Philly or Florida.

10 Now, I'm sorry, and I apologize, I realize I'm  
11 off track. So, yes, as the science has supported,  
12 anterior Prolift works extremely well in the anterior  
13 vaginal compartment, and the literature states quite  
14 clearly that the anatomic results are superior compared  
15 to native tissue repair.

16 Prolift in the posterior compartment, that data  
17 was not as robust, and so when I said limited -- vital  
18 but limited role, vital meaning the most common  
19 problem, the one that causes women the most symptoms is  
20 anterior prolapse, and the data and experience clearly  
21 demonstrate that this is a safe and effective  
22 technique.

23 So the question in my mind was is that what we  
24 concentrate on, do we concentrate on anterior Prolift

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1 as opposed to posterior Prolift. Certainly, those of  
2 us that were looking at things from a pooled analysis  
3 were reaching the conclusion that the posterior  
4 compartment, dyspareunia was a problem with all the  
5 repairs. It wasn't clear to us -- it seemed to us that  
6 it was similar between the two, although we were  
7 getting these reports. So I was just advocating that,  
8 and I think it's supported by my report, that at the  
9 apex and anteriorly, this was a safe and effective  
10 technique in the product, and that's what I meant by  
11 vital because that's the most common, the most  
12 bothersome, limited, let's concentrate on the anterior  
13 and the apex.

14 Q. What did you mean by "Ethicon's  
15 willingness to partner with and support surgeons"?

16 A. Again, many of us felt there was great  
17 value in these summit meetings. I recall that at one  
18 or more of these meetings, some of the key inventors of  
19 both the TVT and the TVM were brought in from Europe,  
20 and we were allowed to listen to them discuss the  
21 development of the product. We were able to ask them  
22 very clinical questions. So I remember asking one of  
23 the TVT individuals who had published on it what do you  
24 tell patients when they can return to work and exercise

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1 and stuff like that. So we found the summit to be  
2 invaluable as an opportunity for colleagues to get  
3 together to further discuss the topic and specifically  
4 to listen to experts both nationally and  
5 internationally.

6 Q. But you would agree that it was an  
7 uncertain time for mesh, correct?

8 MR. SNELL: Object, form.

9 THE WITNESS: I would not agree. I  
10 think at the time I think the FDA's mesh  
11 message, excuse me, was uncertain because,  
12 again, initially they didn't draw -- they  
13 didn't -- they said -- I'm sorry. I lost my  
14 train of thought.

15 BY MR. SCHNIEDERS:

16 Q. The uncertainty you were referring to  
17 was what the FDA's position was; is that what you're  
18 telling me?

19 A. It was unclear whether the additional  
20 cases reported were sling related cases versus vaginal  
21 mesh related cases, as well as what products were  
22 involved.

23 (Document marked for identification as  
24 Toggia Deposition Exhibit No. 29.)

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1 BY MR. SCHNIEDERS:

2 Q. Marking as Exhibit 29 a PowerPoint.

3 Doctor, do you recall this PowerPoint?

4 A. I don't know if I ever gave this power  
5 point in a meeting or not.

6 Q. On the second page of the document you  
7 see it's titled "The Mesh Story."

8 Do you see that?

9 A. Yes.

10 Q. And it's got your name on it as Director  
11 of Urogynecology, Main Line Health System,  
12 Philadelphia, PA right?

13 A. Yes.

14 Q. Are you familiar with The Mesh Story,  
15 was that verbiage you ever used?

16 A. No.

17 MR. SNELL: Do you have a date on this  
18 document?

19 MR. SCHNIEDERS: What's that?

20 MR. SNELL: Do you have a date for this?

21 MR. SCHNIEDERS: I didn't look, to be  
22 honest.

23 MR. SNELL: That's okay.

24 BY MR. SCHNIEDERS:

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1 Q. You see on the bottom right-hand corner,  
2 it's got Ethicon Women's Health & Urology logo, right?

3 A. Yes.

4 Q. We can go off the record, and you can  
5 look over that for a second, if you'd like to, Doctor.

6 MR. SCHNIEDERS: Let's go off the record  
7 so he can look at the PowerPoint.

8 (Brief recess taken at 6:33 p.m.)

9 (Deposition resumes at 6:34 p.m.)

10 BY MR. SCHNIEDERS:

11 Q. Doctor, I think you were saying that you  
12 may have worked on this, you're just not sure, right?

13 A. I don't recognize this.

14 Q. Okay. But suffice it to say, it's got a  
15 Bates number, it was produced to us, and it's titled  
16 "The Mesh Story," and it's got your name on it, right?

17 A. Correct.

18 Q. It could possibly be one of those slide  
19 decks that was made by Ethicon for a presentation they  
20 wanted you to give?

21 A. I would suspect so, yes.

22 Q. Okay. And, typically, when you would  
23 give PowerPoints on behalf of Ethicon, would you do so  
24 with Ethicon's logo on it?

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1           A.       Typically, I am presenting material  
2     prepared by Ethicon in compliance with the FDA  
3     regulations, and I would disclose at the beginning that  
4     I was up there to speak on behalf of the company to  
5     present the company slides.

6           Q.       Okay. And so if you go to the second  
7     page, it says "Content."

8           A.       Yes.

9           Q.       And it gives a few things about -- and  
10    the context, even though it's not dated, and, frankly,  
11    it was my fault for not looking at the Bates number and  
12    custodian, but the context would tell us that this has  
13    got to be after a recent FDA notice, I suspect; is that  
14    fair?

15          A.       I think so. I'm -- I would think that  
16    this is after the October 2008.

17          Q.       So you see the content there it says,  
18    "What does the FDA notice tell us?" And then "Why is  
19    our mesh different?" And is that how you talk in  
20    PowerPoints that you give on behalf of Ethicon --

21          A.       No.

22          Q.       -- you say our mesh?

23          A.       No, I have no ownership. I have no  
24    ownership. That would be an example of something that

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1 I might strike through and say, you know, you need to  
2 be specific that this is Ethicon.

3 Q. And it says, "How does it work? Why is  
4 it designed this way? What does that mean  
5 physiologically?"

6 A. Yes.

7 Q. Going on to the next page it says  
8 "Navigating the Mesh Maze."

9 Did you ever call it the mesh maze?

10 A. No.

11 Q. Bullet point it says, "We have to deal  
12 with competing messages surrounding mesh."

13 Do you agree with that statement?

14 A. I don't know what that means. I read  
15 that as conflicting, but I don't know what that means.

16 Q. Okay. And it says, "Goal is safe and  
17 effective treatment for patients with SUI."

18 A. Yes.

19 Q. And it says, "FDA has issued a Public  
20 Health Notification warning about risks of mesh."

21 A. Yes.

22 Q. "Patients are concerned about mesh  
23 implant. We have to help our customers to understand  
24 how to minimize their risk."

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1           It says our customers right there. Do you  
2   recall from the document we saw before that physicians  
3   are referred to internally as customers?

4           A.       Yeah, I don't know that that's what this  
5   refers to. Again, I'm quite certain this is not  
6   something that I ever presented myself because I would  
7   not -- I would never have used the term customer in any  
8   form. I not have used the our on the previous page. I  
9   would not have used our customers.

10           This may have been an outline or a markup of  
11   something that they were thinking about. I can't tell  
12   you I ever saw this. I have no recollection of seeing  
13   this. This is certainly not something I've presented.

14           Q.       But fair to say that it says we have to  
15   help our customers to understand how to minimize their  
16   risk. Fair reading of that is that Ethicon is trying  
17   to help doctors that use their products to minimize  
18   their risk, right?

19                   MR. SNELL: Foundation.

20                   THE WITNESS: I don't agree, no.

21   BY MR. SCHNIEDERS:

22           Q.       What do you think it means?

23           A.       I don't know the context, sir.

24           Q.       Okay. Well, that's fair.



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1           A.       As a surgeon, I look at this as we need  
2   to talk about women and help women to understand and --  
3   I mean, I'm really lost. I'm so sorry. I have no  
4   idea.

5           Q.       Does it make you mad that Ethicon put  
6   your name on something like this?

7           A.       No. I mean, I don't -- again, this may  
8   have been an idea that they floated by me. I don't  
9   know.

10          Q.       So the next slide goes on and talks  
11   about the FDA alert, October of 2008.

12               And then the next slide basically breaks down  
13   what that alert said, FDA Recommendations, be vigilant  
14   for potential adverse events (erosion, infection).  
15   Watch for perforation from tools. Inform patients that  
16   mesh implantation is permanent and that some  
17   complications may require additional surgery that may  
18   or may not correct the complication. Inform patients  
19   about potential for serious complications affecting  
20   QOL, quality of life (dyspareunia, scarring). Provide  
21   patient with a written copy of the patient labeling.

22               Do you provide your patients with written  
23   copies of the patient labeling?

24          A.       I think that -- again, I think what

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1     they've done here is they have provided a summary of  
2     what the FDA had written. In our practice, we do have  
3     readily available each of the FDA safety warnings. We  
4     have the position statements from our organization. We  
5     have brochures from Ethicon on the TVT, which would  
6     include the labeling information. So those are  
7     discussed and, when appropriate, offered to the  
8     patient.

9             Q.       If you go to the next page it says, "We  
10    should be counseling patients differently about mesh.  
11    When selecting a sling 'what's left behind' matters  
12    more than the delivery system."

13            What does that mean to you, Doctor?

14            A.       To me what this means, and I think  
15    you'll get your answer towards the end of this  
16    presentation, is that the majority of the science  
17    demonstrating the safety and efficacy of the TVT  
18    product is specifically based upon the TVT product.  
19    However, other companies that have similar products are  
20    sort of borrowing from research that was done on TVT,  
21    and so I think what we were speaking to here is the  
22    fact that we have a wealth of data on TVT specifically.

23            And so when we talk to people about sling  
24    choices, and, remember, there are 49 slings on the

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1 market or were on the market, what do we tell people,  
2 what do we tell, do we tell them we're going to do a  
3 sling, we're going to do a synthetic sling, we're  
4 specifically using one versus another.

5           You know, this was -- the use of implants --  
6 we've used implants from the '50s, but it was becoming  
7 more commonplace. So as a surgeon, our process for  
8 informed consent and discussion was evolving. We all  
9 had different methods. When we would go to the summit  
10 meeting, different people would say, this is how I  
11 present the information, this is how I present the  
12 information, this is what I tell the patient, and I  
13 think that that's probably what they were -- I think  
14 that they were specifically saying, look, we have the  
15 data, we've got -- at the time we have 40 some odd  
16 clinical trials specifically with our product, whereas  
17 competitors may have less than ten products.

18           Q.       And here it says "meshes are different  
19 and should be assessed by their own clinical outcomes,"  
20 which fits in with what you're saying right now, right?

21           A.       Mm-hmm.

22           Q.       And then the fourth category there it  
23 says, "In a category of slings where 'Level I Evidence'  
24 exists with proven safety and efficacy, why accept a

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1 mesh without outcomes data?"

2 Level 1 evidence is something that you say  
3 quite a bit, right?

4 A. Yes.

5 Q. And the next page, "All meshes are not  
6 equal." And then it goes on to show the pictures of  
7 the different meshes, "All are polypropylene...but  
8 meshes have differences."

9 Do you recall this slide?

10 A. I mean, this slide has come and gone  
11 throughout the history of these discussions as far as  
12 specifically how these products are knitted.

13 Q. And do you believe that AMS or Boston  
14 Scientific or Bard's mesh is different than Ethicon's?

15 MR. SNELL: Form.

16 THE WITNESS: I don't have much  
17 experience using those products. Again -- I  
18 just, again, I'm an evidence-based guy, and you  
19 can see just clinically my entire experience, I  
20 stick with what seems to have the most  
21 evidence, so they're all polypropylene, they  
22 all are Type I Amid meshes, macroporous. You  
23 know, I'm not aware of major differences  
24 between them.

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1 BY MR. SCHNIEDERS:

2 Q. Do you believe that AMS or Boston  
3 Scientific or Bard's mesh can cause complications?

4 A. I don't, no, based upon my extensive  
5 review of the literature and the report that I've  
6 presented previously. It's not the material.

7 Q. It goes on it says, "What are the  
8 mechanical properties of an ideal sling design?" And  
9 it's got four bullet points and tell me if you agree  
10 with these, that it "incorporates into tissue."

11 Do you agree?

12 A. Sorry. I lost my place.

13 Q. It's right after the pictures of the  
14 mesh. It's titled "What are the mechanical properties  
15 of an ideal sling design?"

16 Do you see it, Doctor?

17 A. I do. I mean, I believe that these are  
18 points for discussion. So, you know, is it important,  
19 you know, how a sling incorporates into the tissue, is  
20 it important the stiffness, is there a relationship  
21 between stiff and non-stiff? These are all the things  
22 that we were exploring.

23 Obviously, we were all comfortable that the  
24 introduction of midurethral slings was a major advance

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1 in this field. We were aware of what was being  
2 reported to the FDA, so we were saying to ourselves,  
3 okay, we're on the front line, let's dig into this. I  
4 can't tell you that we drew any direct conclusions, but  
5 these were the questions that we were asking.

6 Q. But, sitting here today, you can't point  
7 to those four things as the properties of an ideal  
8 sling design?

9 A. I'm sorry, I mean, yes. Obviously, it  
10 is important how the sling incorporates itself into  
11 tissue. You know, to me it just speaks to  
12 biotolerability, and, yes, that's important as well.  
13 Remember that around this period of time there were a  
14 couple slings, ObTape, that was taken off the market,  
15 had a very, very different design. The original  
16 Protogen sling, which is the precursor, was taken off  
17 the market. I vaguely remember that somebody had a  
18 silicone-coated sling that was not used, you know,  
19 after a while. So, again, obviously, these type of  
20 things facilitate discussion.

21 Q. If you go two more slides down, it says,  
22 "Gynecare TVT Tension-free Support for Incontinence  
23 Mesh: Unique Properties." It says, "Measurable  
24 differences from other polypropylene meshes, largest

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1 pore size, lowest stiffness, highest elongation."

2 Are those important to you as a physician?

3 A. Again, I did not write this information,  
4 you know, what we considered to be important clinically  
5 and what the literature supports is that we're using a  
6 macroporous product. I mean, is there a difference  
7 between 1,100 and 1,300 clinically? I don't believe  
8 so. Is there a significance to stiffness? I don't  
9 know. Elongation, I don't know either. Is it true  
10 that the TVT mesh has the largest pore size? Yes.  
11 That it has the lowest stiffness? You know, my  
12 recollection, yes. I think those statements are  
13 supported by the title. I don't think it speaks to any  
14 kind of clinical.

15 Q. Significance?

16 A. Application, clinical significance,  
17 clinical difference.

18 Q. Can you go back two pages to the page  
19 that looks like the chart like this?

20 A. Right.

21 Q. You see there under the asterisk at the  
22 bottom it says, AMS mesh was tested without tensioning  
23 suture. In another study comparison when measured with  
24 the tensioning suture SPARC has a stiffness of

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1 .53 nanograms per milliliter and Gynecare TVT  
2 Tension-free Support for Incontinence has a stiffness  
3 of .23 nanograms per milliliter. This is a highly  
4 significant difference, and it gives a P value there.

5 You see that?

6 A. Yes.

7 Q. So, apparently, it wasn't you, but  
8 whoever put this PowerPoint together and put your name  
9 on it felt that that was an important difference,  
10 right?

11 A. Well, you know, yes. I mean, there's --  
12 but there's a difference between clinically significant  
13 and the fact that -- I mean, that the numbers are  
14 highly significant difference. As we go through this,  
15 as we had -- as you brought up earlier this afternoon,  
16 there was a document that suggested that I participated  
17 in a luncheon discussion at a meeting. It may be that  
18 this was something that was being considered for that  
19 venue. I don't know. I have no recollection that this  
20 is actually what I presented, but perhaps there's a  
21 relation -- we don't have a date for this.

22 Q. Finishing up, there's a page that is  
23 right before what I've called the footnotes or the  
24 credits I guess at the end, it's titled -- it says



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1 "Prolene polypropylene mesh is highly inert."

2 You see that page, Doctor?

3 A. Mm-hmm.

4 Q. And then it says, "treated over  
5 1.5 million patients," and then it says "longest term  
6 follow-up of any mesh at 11.5 years," and "The most  
7 'Level I Evidence' with 41 RCTs." Now, that bottom  
8 cite, Number 7, if you go over to the references, it  
9 says there was a PubMed search, and you can see PubMed  
10 search was from 1/26 of '09 through 2/20 of '09, which  
11 gives us a time frame for when this would have  
12 occurred. I'm assuming you didn't run that PubMed  
13 search, right?

14 A. That is correct.

15 MR. SCHNIEDERS: Let me take five.

16 (Brief recess taken at 6:51 p.m.)

17 (Deposition resumes at 6:57 p.m.)

18 (Document marked for identification as  
19 Toggia Deposition Exhibit No. 30.)

20 BY MR. SCHNIEDERS:

21 Q. I have just marked as Exhibit 30 a  
22 ProPublica document or it comes from the ProPublica  
23 database where you can type in doctors' names and it  
24 shows some of the payments they've received from the

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1 past couple of years.

2 Are you familiar with this type of document?

3 A. I am, I am.

4 Q. If you go to the second page, they don't  
5 print out very nicely every time, but on the second  
6 page it states that from August of 2013 through  
7 December of 2014, you received a total of 137 payments  
8 for 45,967 -- \$45,976.

9 Does that sound about right to you or sound  
10 high, sound low?

11 A. And, again, not wanting to be  
12 argumentative, I take issue with the 137 payments. I  
13 think that if somebody brought lunch to my office or to  
14 my office staff, that perhaps that might be counted as  
15 a payment.

16 Q. I think, in fact, it is. If you look  
17 under down here under types of payments, it's going to  
18 tell you exactly what it was.

19 A. Right. I think also I do recall, and it  
20 may not be specifically this time period, that Pfizer  
21 had floated a study by me. We submitted the  
22 information to the Lankenau Institute of Medical  
23 Research. They paid that institute \$2,000 for their  
24 review of the protocol. We would not participate, but

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1 it was reported as income to me, but I never saw that  
2 income.

3 Q. So I'm going to ask you -- it lists  
4 through every single payment here and talks it through.

5 A. Sure.

6 Q. I'm not going to ask you about each  
7 individual payment.

8 A. Sure.

9 Q. I want to highlight or mention the  
10 company that's listed just to see if that's something  
11 that sounds right, like you would have received  
12 something from that company?

13 A. I mean, I see stuff on here that I  
14 clearly had no involvement with, but go ahead.

15 Q. That's fine, just tell me as we go  
16 along.

17 A. Sure.

18 MR. SNELL: Note my continuing objection  
19 as to the foundation, accuracy of this  
20 document, and move motion in limine to preclude  
21 this document.

22 Go ahead.

23 BY MR. SCHNIEDERS:

24 Q. Astellas Pharma US, I think we talked

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1 about them earlier; is that right?

2 A. Yes.

3 Q. AMS?

4 A. I'm sorry. The question is specifically  
5 is did I?

6 Q. Do you recall consulting for American  
7 Medical Systems Inc.?

8 A. Yes. Some of them, for example, Elevate  
9 is AMS. I never consulted. That is not a consulting  
10 thing, \$19. That was maybe a lunch, I don't know. I  
11 honestly don't know.

12 Q. Uroplasty, Inc. do you recall that?

13 A. Yes.

14 Q. Is Uroplasty, Inc. a device  
15 manufacturer?

16 A. Uroplasty was a device manufacturer.  
17 They were renamed Cogentix, C-o-g-e-n-t-i-x, and I  
18 consulted with them on productional education slide  
19 development.

20 Q. There were a handful of Ethicon on here.  
21 There's one on March 25th of 2014, which is Page 14 of  
22 44 at the top. It says uterine surgery for \$107?

23 A. I'm sorry, where?

24 Q. If you go to the numbering up here,

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1 Number 14, and it's the top one.

2 A. I'm sorry. And this was which year?

3 Q. March 25th of 2014.

4 A. Got you. I mean, there's probably  
5 another physician in my office. At that time there  
6 were two other physicians in my practice, and they  
7 might have been talking to them about either the  
8 morcellator product, that wouldn't be me. That's not  
9 something that I would have likely participated in.

10 Q. And I would note that and consistent  
11 with what you said earlier that Astellas seems to be  
12 the name that comes up the most often.

13 Does that sound right to you?

14 A. Yes, during this time period, probably  
15 the work that I did was with overactive bladder having  
16 participated in some of the research previously.

17 Q. Looks like there was food related to a  
18 drug called Toviaz from Pfizer.

19 Do you recall that?

20 A. Yeah, that's food provided to my office  
21 staff. I may or may not have been there.

22 Q. Same thing with regard to Warner  
23 Chilcott for a drug called Enablex?

24 A. Yes.

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1 Q. Noven Pharmaceuticals for a drug called  
2 Brisdelle?

3 A. That's not me. Brisdelle I believe is a  
4 birth control pill. That's not accurate. I never sat  
5 in on a lunch for -- no, I'm sorry, Brisdelle, PMS  
6 treatment perhaps. Again, probably marketed towards my  
7 junior partner. Forteo, not me.

8 Q. Forteo?

9 A. No, not me. I have no idea what  
10 Xartemis is, never heard of that.

11 Q. Is that the one that's Mallinckrodt?

12 A. I have no idea.

13 Adhesion prevention, I don't recognize that at  
14 all.

15 Q. Allergen for Botox?

16 A. I've never used Botox. I don't believe  
17 that would be myself either. This is not that  
18 accurate.

19 Q. Just so you're aware, for your own sake,  
20 you can go and contest anything that's not accurate.

21 A. I appreciate that. Thank you. Yes.

22 Q. If you do feel that way.

23 That's the majority of the companies there.

24 Lastly, Doctor, when you give a risk-benefit

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1 discussion to any of your female patients about the  
2 potential of receiving a TVT device or receiving  
3 Gynemesh PS, do you disclose to them that you had a  
4 financial relationship with Ethicon?

5 A. I do.

6 Q. And what do you tell them?

7 A. I tell them that I have been involved  
8 with professional education, research study, that I've  
9 consulted on designs, development of such products. I  
10 disclose as much as, you know, they're interested in  
11 hearing.

12 Q. No amounts, I assume, right?

13 A. I don't tell them specific amounts.  
14 Obviously, these are all public records. You can find  
15 out how much Medicare paid me last month if you wanted  
16 to.

17 MR. SCHNIEDERS: Doctor, I think my time  
18 is up. I have no further questions. Thank you  
19 for your time.

20 BY MR. SNELL:

21 Q. Doctor, I'm just going to ask a few  
22 follow-up questions on a couple topics.

23 Doctor, I'll represent to you that depositions  
24 of the plaintiffs' experts are ongoing. I know you've

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1    been provided Dr. Ostergard's deposition, but there are  
2    many other depositions going on, and it will be, I'll  
3    represent, sent to you.

4            Could you plan to reserve the right to issue  
5    any new or updated opinions based on depositions of the  
6    plaintiffs' experts?

7            MR. SCHNIEDERS: Object to the form.

8            THE WITNESS: Yes, I would say that  
9    sounds fair.

10   BY MR. SNELL:

11           Q.     And will you look at any new studies  
12   that come out that you may or may not find to be  
13   pertinent to your opinions?

14           MR. SCHNIEDERS: Object to the form.

15           THE WITNESS: Yes, I read this  
16   literature frequently so...

17   BY MR. SNELL:

18           Q.     You were asked questions about if you  
19   were provided company documents. Besides the IFUs, the  
20   professional education materials, the slide decks, the  
21   videos and all the stuff that are on the thumb drive  
22   somewhere that we're going to put in the box as  
23   Exhibit 4, I just want to call to your attention. So  
24   in Dr. Ostergard's materials that were provided to you,



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1 are there company documents and things of that nature  
2 as well?

3 MR. SCHNIEDERS: Object to the form.

4 THE WITNESS: I mean, obviously, the  
5 Prolift documents, these are slides on Prolift,  
6 so, yes. There are various e-mails.

7 BY MR. SNELL:

8 Q. You were asked about your expertise in  
9 various areas. Let me ask you about that.

10 Do you believe you're an expert in how the  
11 chemical polypropylene the polymer performs in pelvic  
12 surgery in a woman?

13 MR. SCHNIEDERS: Object to form.

14 THE WITNESS: Yes, I do believe I'm an  
15 expert in that.

16 BY MR. SCHNIEDERS:

17 Q. Besides, obviously, your testimony that  
18 you've utilized polypropylene over many decades before  
19 pelvic surgery, have you also researched that topic in  
20 the reliable scientific medical literature?

21 MR. SCHNIEDERS: Object to the form.

22 THE WITNESS: Yes, I have.

23 BY MR. SNELL:

24 Q. Have you analyzed the design of the

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1 devices that utilize the Ethicon polypropylene?

2 MR. SCHNIEDERS: Object to the form.

3 THE WITNESS: Yes, I have.

4 BY MR. SNELL:

5 Q. You were asked if you're an expert in  
6 polymer chemistry. Do you believe you're an expert in  
7 that field?

8 MR. SCHNIEDERS: Object to the form.

9 THE WITNESS: As it pertains to what  
10 we're discussing here and its intended use,  
11 yes, I am.

12 BY MR. SNELL:

13 Q. And before you even went to medical  
14 school, I think you testified you have a degree in  
15 biochemistry as well?

16 A. Correct.

17 Q. Do you believe you have a very good  
18 working knowledge and understanding of chemistry?

19 A. Yes, I have.

20 Q. Including the chemistry of polypropylene  
21 and what -- the atoms or molecules it's made up of?

22 A. That's correct. I did research as an  
23 undergraduate in silastic plastic delivery systems.

24 Q. You talked some in this deposition about

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1 your consulting and evaluation of the development and  
2 design of sling and prolapse devices.

3 In your earlier deposition, you recall covering  
4 that subject as well?

5 A. I do, yes.

6 Q. Do you stand by your testimony from your  
7 earlier deposition in the Mullens case about the  
8 various design and development work you did?

9 MR. SCHNIEDERS: Object to the form.

10 THE WITNESS: Yes, I believe we covered  
11 that pretty extensively.

12 BY MR. SNELL:

13 Q. Do you recollect in that testimony you  
14 discussed that you were involved in the design  
15 validation of the Gynemesh M mesh?

16 MR. SCHNIEDERS: Object to the form.

17 THE WITNESS: Yes.

18 BY MR. SNELL:

19 Q. And is that a prolapse mesh similar to  
20 Gynemesh PS?

21 MR. SCHNIEDERS: Object to the form.

22 THE WITNESS: Yes.

23 BY MR. SNELL:

24 Q. Do you recollect testifying and telling

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1 the lawyers under oath that in your role as being one  
2 of the design validation surgeons, you assessed the  
3 suitability, safety, efficacy and adequacy of the  
4 design of that product?

5 MR. SCHNIEDERS: Object to the form.

6 THE WITNESS: I did, yes.

7 BY MR. SNELL:

8 Q. Do you also recall and recollect your  
9 testimony that in the design validation activities you  
10 performed on the prolapse mesh for Ethicon, you also  
11 assessed the instructions for use as to its adequacy  
12 and clarity and how it laid out instructions?

13 MR. SCHNIEDERS: Object to the form.

14 THE WITNESS: Yes, I did.

15 BY MR. SNELL:

16 Q. Do you recollect that you testified that  
17 in connection with your evaluation of the IFU for the  
18 prolapse device, you were asked whether it was clear or  
19 cohesive or accurate?

20 MR. SCHNIEDERS: Object to the form.

21 THE WITNESS: Yes, I did.

22 BY MR. SNELL:

23 Q. And besides the prolapse mesh, I think  
24 you testified here today and you testified earlier, you

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1 have consulted and evaluated the design of other  
2 Ethicon pelvic floor products over various time  
3 periods?

4 MR. SCHNIEDERS: Object to the form.

5 THE WITNESS: Yes, I have.

6 BY MR. SNELL:

7 Q. For example, you testified about your  
8 design evaluation and your work with the TVT Exact  
9 product for stress urinary incontinence?

10 MR. SCHNIEDERS: Object to the form.

11 THE WITNESS: Yes, starting from the  
12 concept of the design all the way through the  
13 engineering, all the way through the  
14 suitability of the product and the professional  
15 education component of that, which included the  
16 teaching, the filming of the video  
17 demonstrating the technique.

18 BY MR. SNELL:

19 Q. And would that professional education  
20 also include the instructions for use?

21 MR. SCHNIEDERS: Object to the form.

22 THE WITNESS: Yes, it did include the  
23 instructions for use.

24 BY MR. SNELL:

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1           Q.       And so do you believe you're an expert  
2   and qualified to opine on the adequacy of the  
3   instructions for use for the Gynemesh PS and Prolift  
4   and the TVT product?

5                   MR. SCHNIEDERS: Object to the form.

6                   THE WITNESS: Yes, I will agree with  
7                   that.

8   BY MR. SNELL:

9           Q.       And did you actually teach the IFU  
10   during your professional education activities for  
11   various products in addition to the discussions or I  
12   think you called them proctorships as well?

13                   MR. SCHNIEDERS: Object to the form.

14                   THE WITNESS: Yes, I did.

15   BY MR. SNELL:

16           Q.       And I think we've seen or you produced  
17   earlier, as I recall, slide decks, maybe more than one.  
18   Do you recollect during your professional education  
19   activities talking to pelvic floor surgeons about the  
20   potential risk and how to utilize and insert these  
21   devices?

22                   MR. SCHNIEDERS: Object to the form.

23                   THE WITNESS: Yes. We specifically  
24                   would go over techniques, strategies to

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1 minimize, strategies to recognize the  
2 potential.

3 BY MR. SNELL:

4 Q. You were asked about the TVT Secur  
5 randomized control trial.

6 Do you recollect that?

7 A. I was asked about the security trial,  
8 which compared TVT retropubic with TVT Secur.

9 Q. Was your site paid by Ethicon? I just  
10 want to understand, because I think there was  
11 questioning about that, and I got a little unclear.

12 A. I understand.

13 MR. SCHNIEDERS: Object to the form.

14 THE WITNESS: My recollection is that we  
15 were paid by the Cleveland Clinic. I might  
16 have earlier mentioned that the money came from  
17 the foundation, but I do believe that the  
18 actual payments came through the Cleveland  
19 Clinic Foundation.

20 BY MR. SNELL:

21 Q. You were asked questions about whether  
22 you were an expert in pathology. Let me ask you this:  
23 In your review of the medical literature, have you  
24 reviewed the pathology papers with the

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1 photomicrographs, such as the Clave study?

2 MR. SCHNIEDERS: Object to the form.

3 THE WITNESS: Yes, I've reviewed the  
4 studies as we've listed them involving the  
5 scanning electron microscopy using the Fournier  
6 method of analysis, the optical method of  
7 analysis as well, the histologic -- several  
8 histologic studies.

9 BY MR. SNELL:

10 Q. And based upon your medical education  
11 and training, were you able to adequately evaluate  
12 those pathologic studies?

13 MR. SCHNIEDERS: Object to the form.

14 THE WITNESS: Yes, I think I have an  
15 excellent working knowledge of those topics.

16 MR. SNELL: That's all I have. Thank  
17 you for your time.

18 (Witness excused.)

19 (Deposition concluded at 7:17 p.m.)

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1 C E R T I F I C A T I O N

2 I, MARGARET M. REIHL, a Registered  
3 Professional Reporter, Certified Realtime  
4 Reporter, Certified Shorthand Reporter,  
5 Certified LiveNote Reporter and Notary Public,  
6 do hereby certify that the foregoing is a true  
7 and accurate transcript of the testimony as  
8 taken stenographically by and before me at the  
9 time, place, and on the date hereinbefore set  
10 forth.

11 I DO FURTHER CERTIFY that I am  
12 neither a relative nor employee nor attorney  
13 nor counsel of any of the parties to this  
14 action, and that I am neither a relative nor  
15 employee of such attorney or counsel, and that  
16 I am not financially interested in the action.

17

18

19

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Margaret M. Reihl, RPR, CRR, CLR

20

CSR #XI01497 Notary Public

21

22

23

24

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ACKNOWLEDGMENT OF DEPONENT

I, MARC R. TOGLIA, M.D., do hereby  
certify that I have read the foregoing pages,  
and that the same is a correct transcription of  
the answers given by me to the questions  
therein propounded, except for the corrections  
or changes in form or substance, if any, noted  
in the attached Errata Sheet.

\_\_\_\_\_  
MARC R. TOGLIA, M.D. DATE

Subscribed and sworn to before me this

\_\_\_\_\_ day of \_\_\_\_\_, 2016.

My commission expires:\_\_\_\_\_

\_\_\_\_\_  
Notary Public